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(54) **SYRINGE SAFETY DEVICE**

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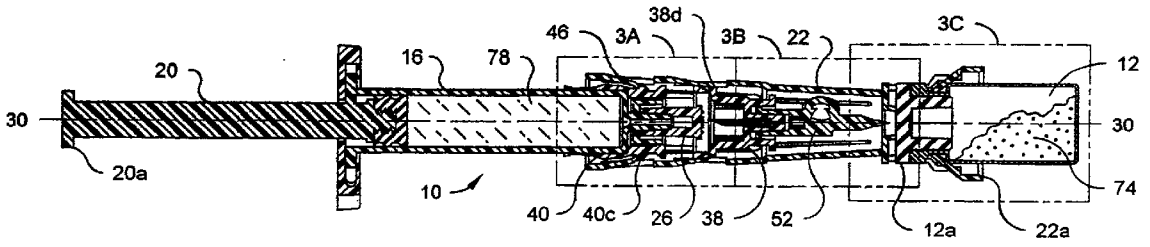
(57) **ABSTRACT**

A tip cap for a syringe that limits contact between the syringe and a needle tip, wherein the needle tip penetrates the tip cap to one of dispense medication out of the syringe and draw medication into of the syringe. The syringe includes a luer cone extending from a barrel of the syringe. The tip cap includes a penetration wall and a generally cylindrical sleeve extending generally perpendicularly from the penetration wall adjacent a periphery of the penetration wall. The cylindrical sleeve includes a radially, inwardly extending locating shoulder on an inner surface that is positioned a predetermined distance from the penetration wall. The locating shoulder engages an end of the luer cone in an operating position. The penetration wall, cylindrical sleeve and luer cone define a receiving space within which the needle tip is positionable.



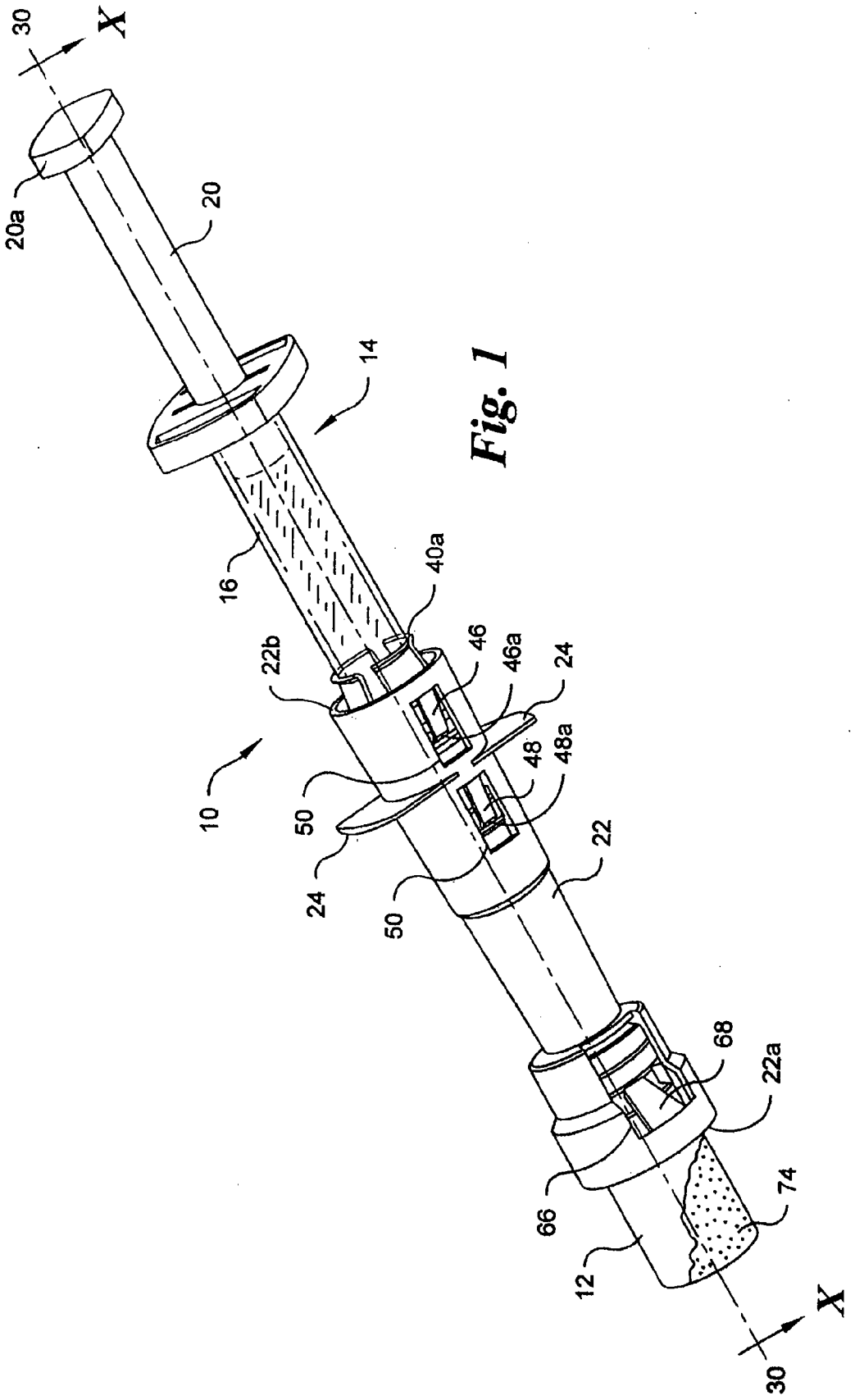

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Fig. 1

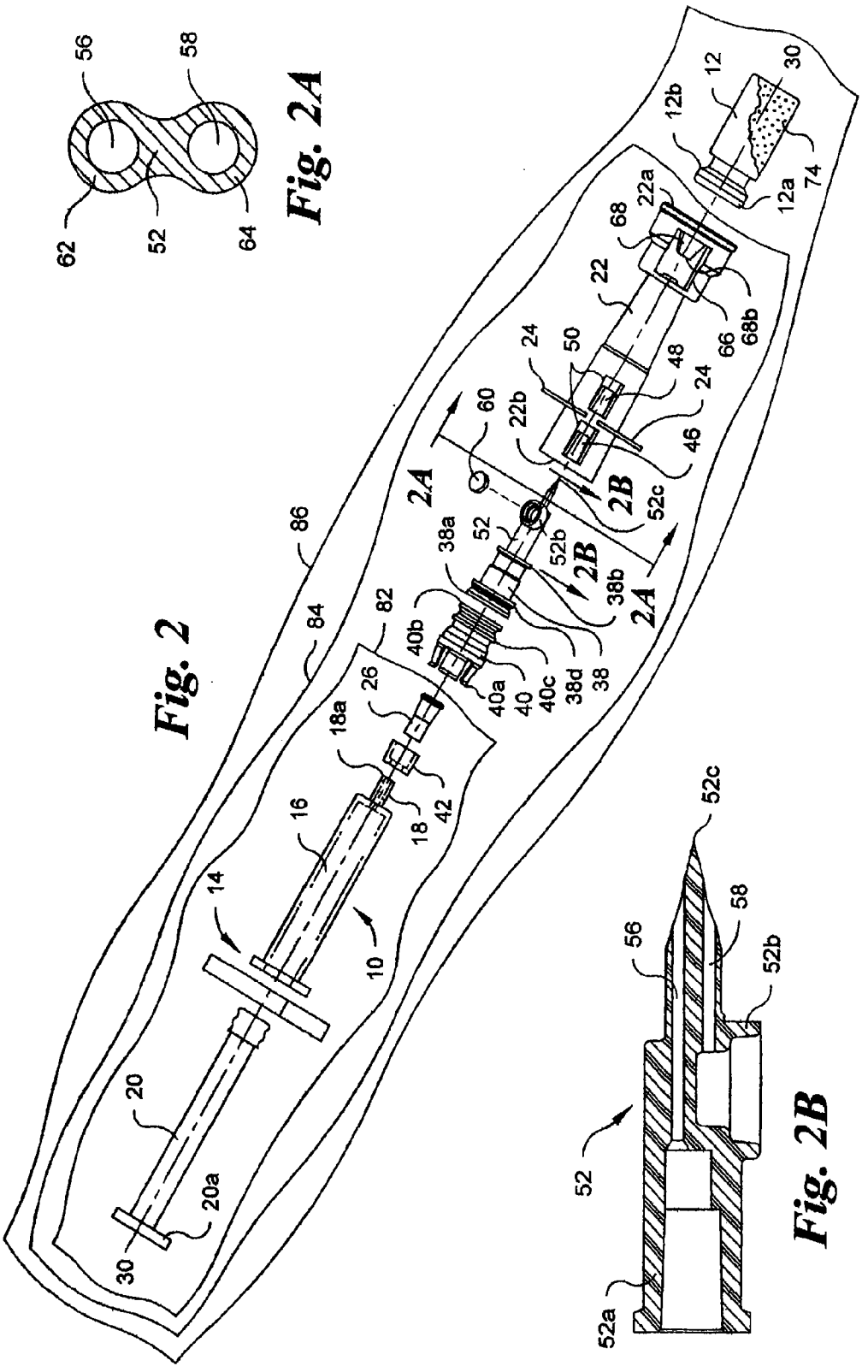
Fig. 2
Fig. 2A
Fig. 2B
2A
2B
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12a
12b
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38b
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40b
40c
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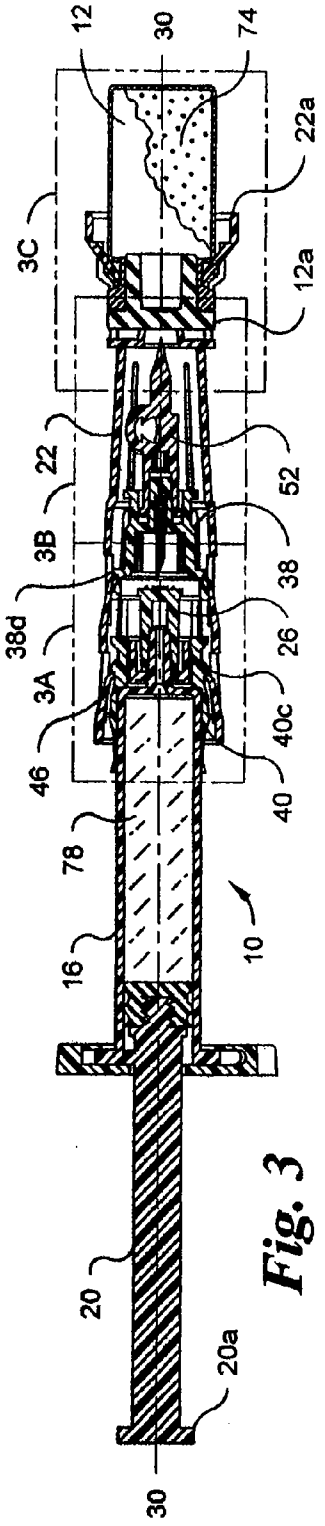


Fig. 3

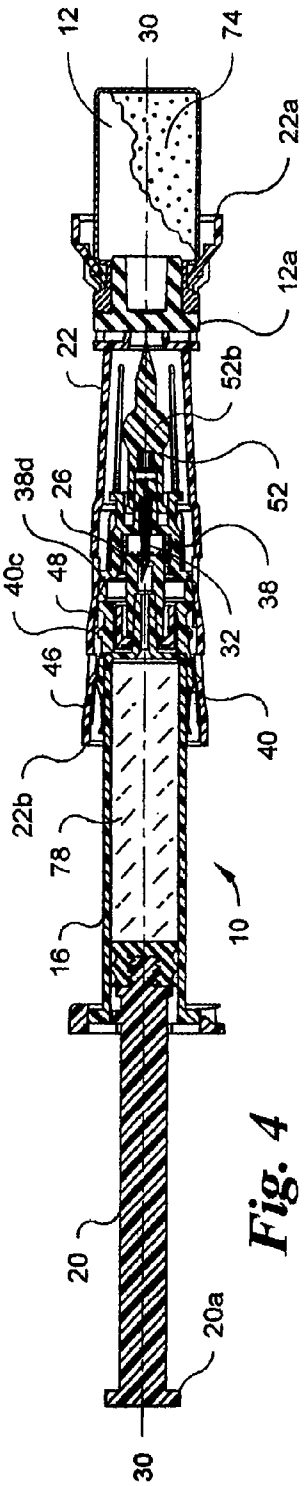


Fig. 4

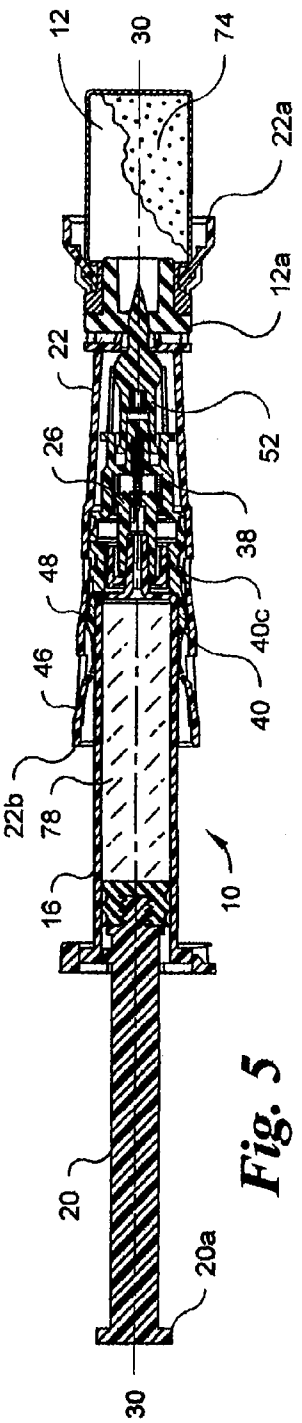


Fig. 5

Fig. 3A

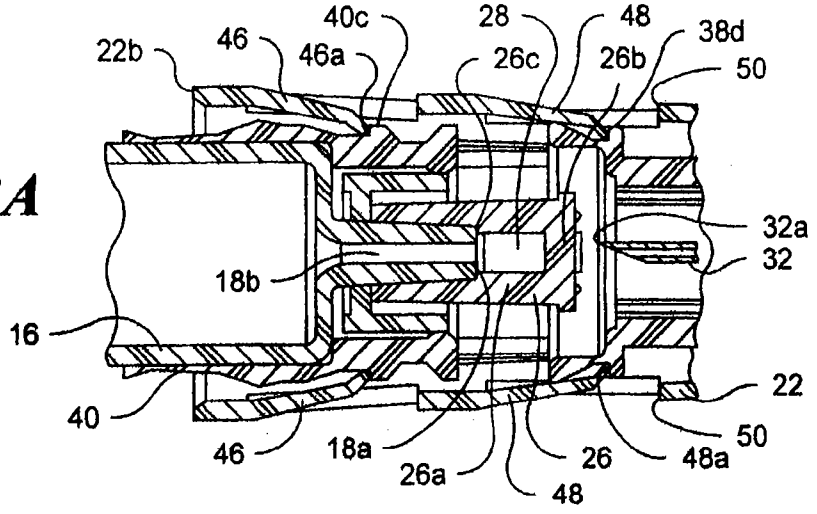


Fig. 3B

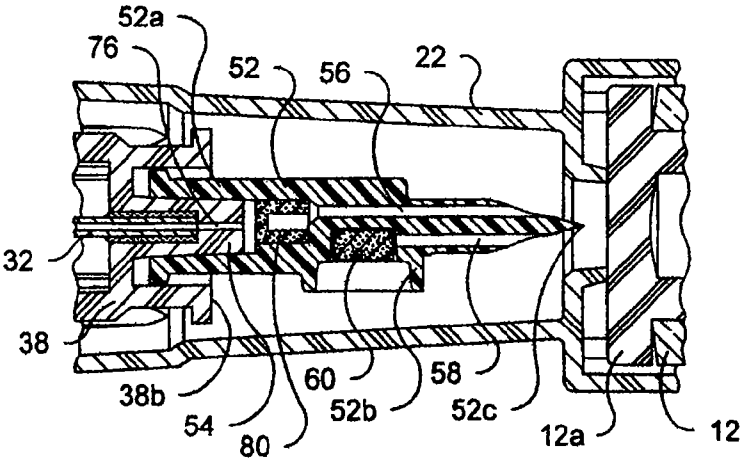
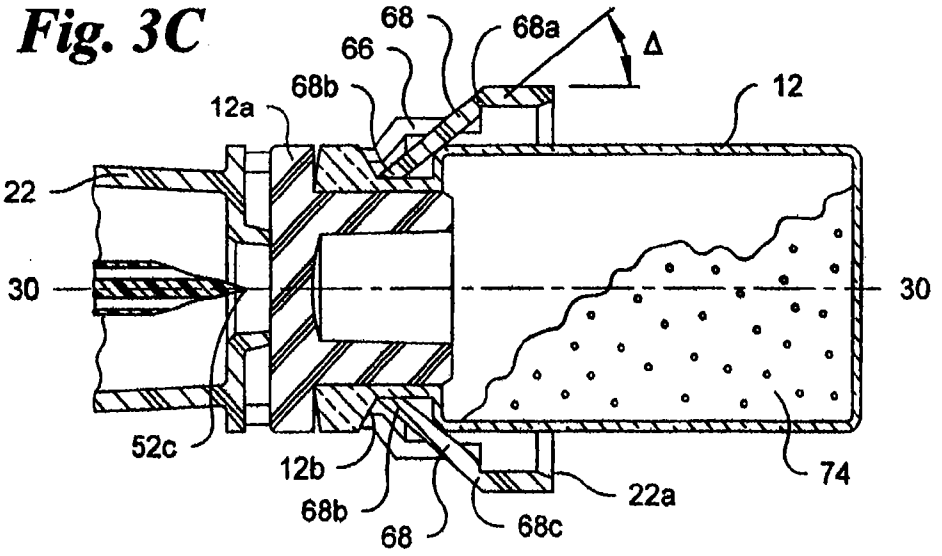
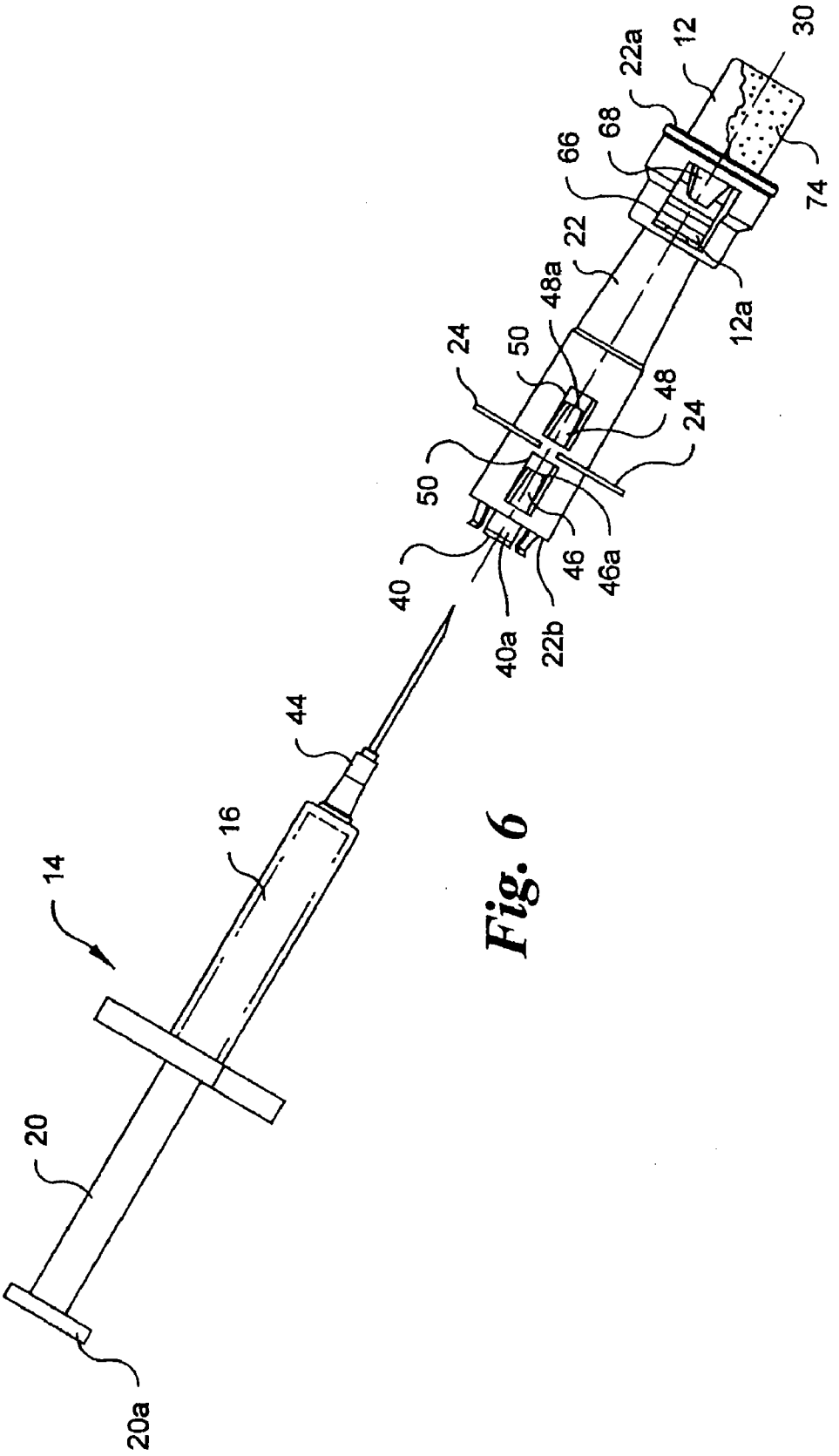


Fig. 3C

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48a
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40a
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14
20
20a

Fig. 6

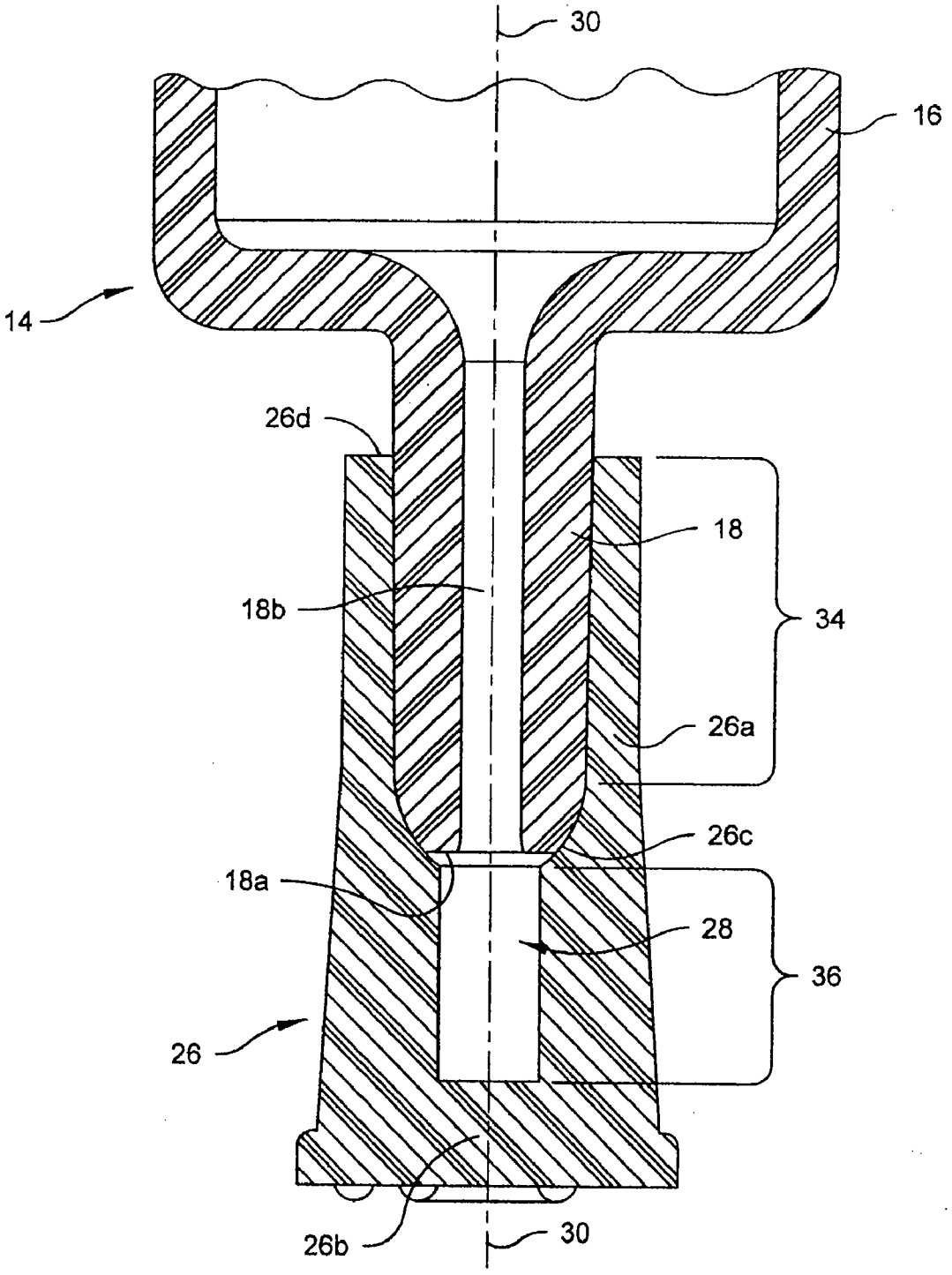

Fig. 7

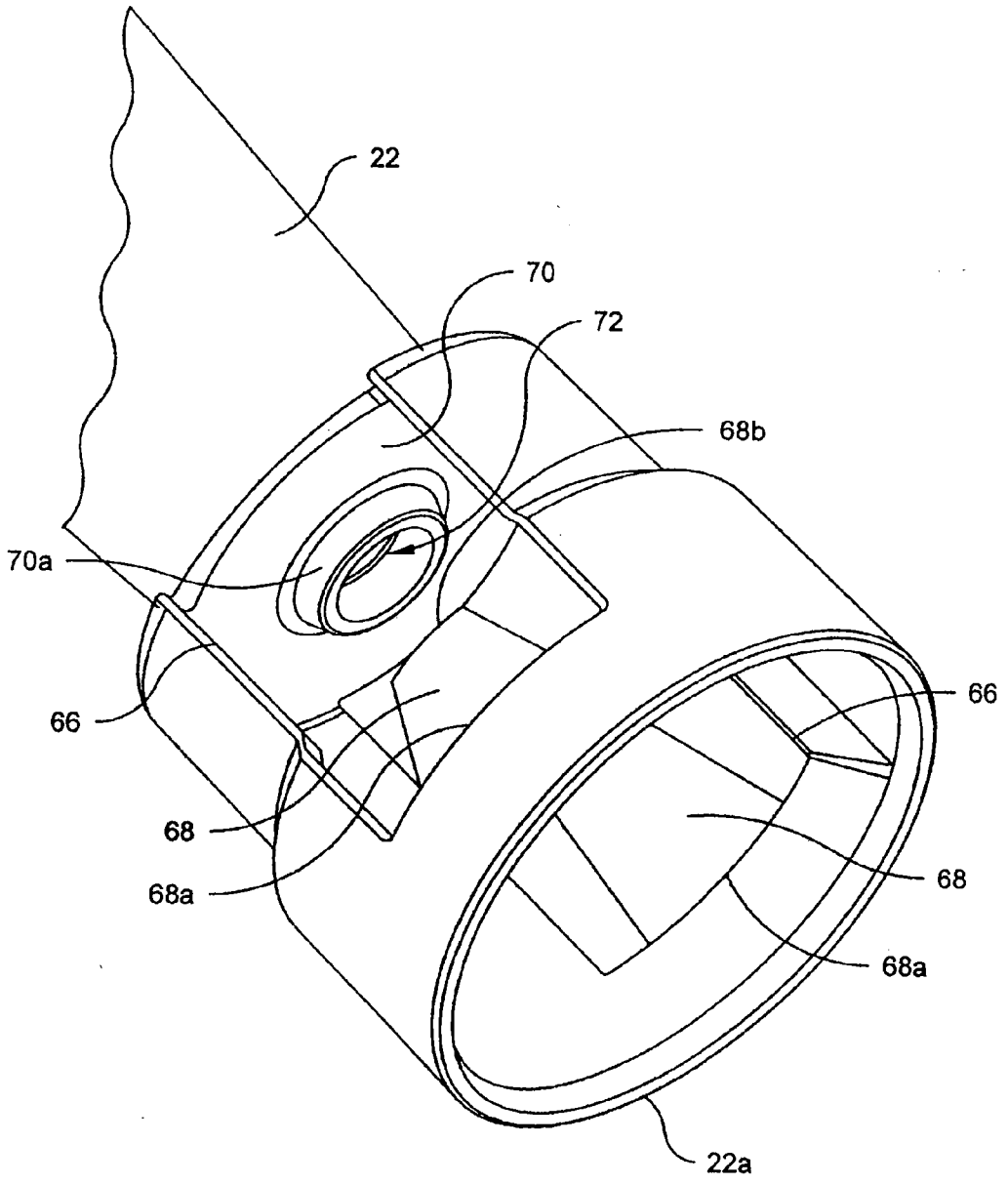

Fig. 8

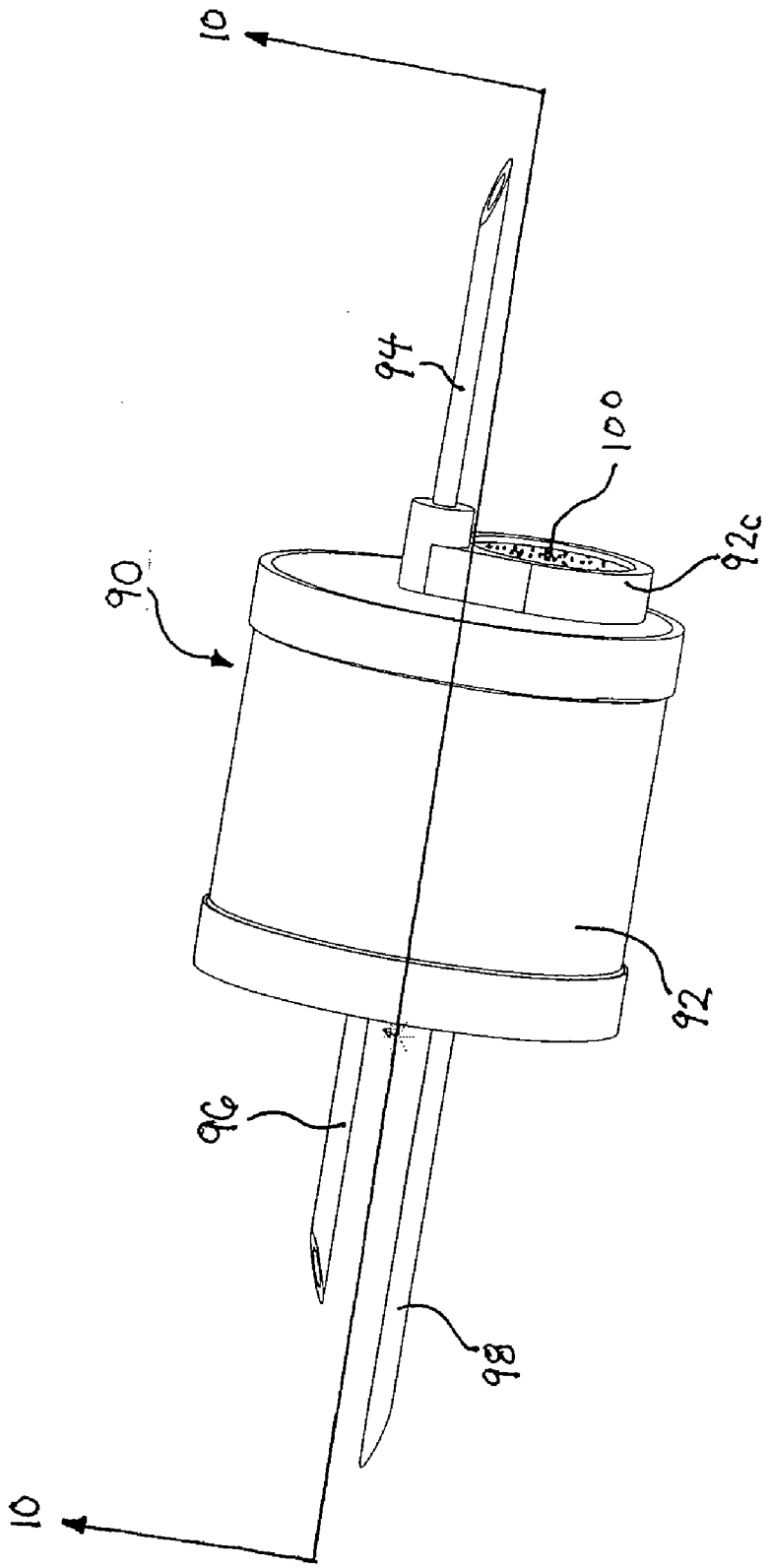

Fig. 9

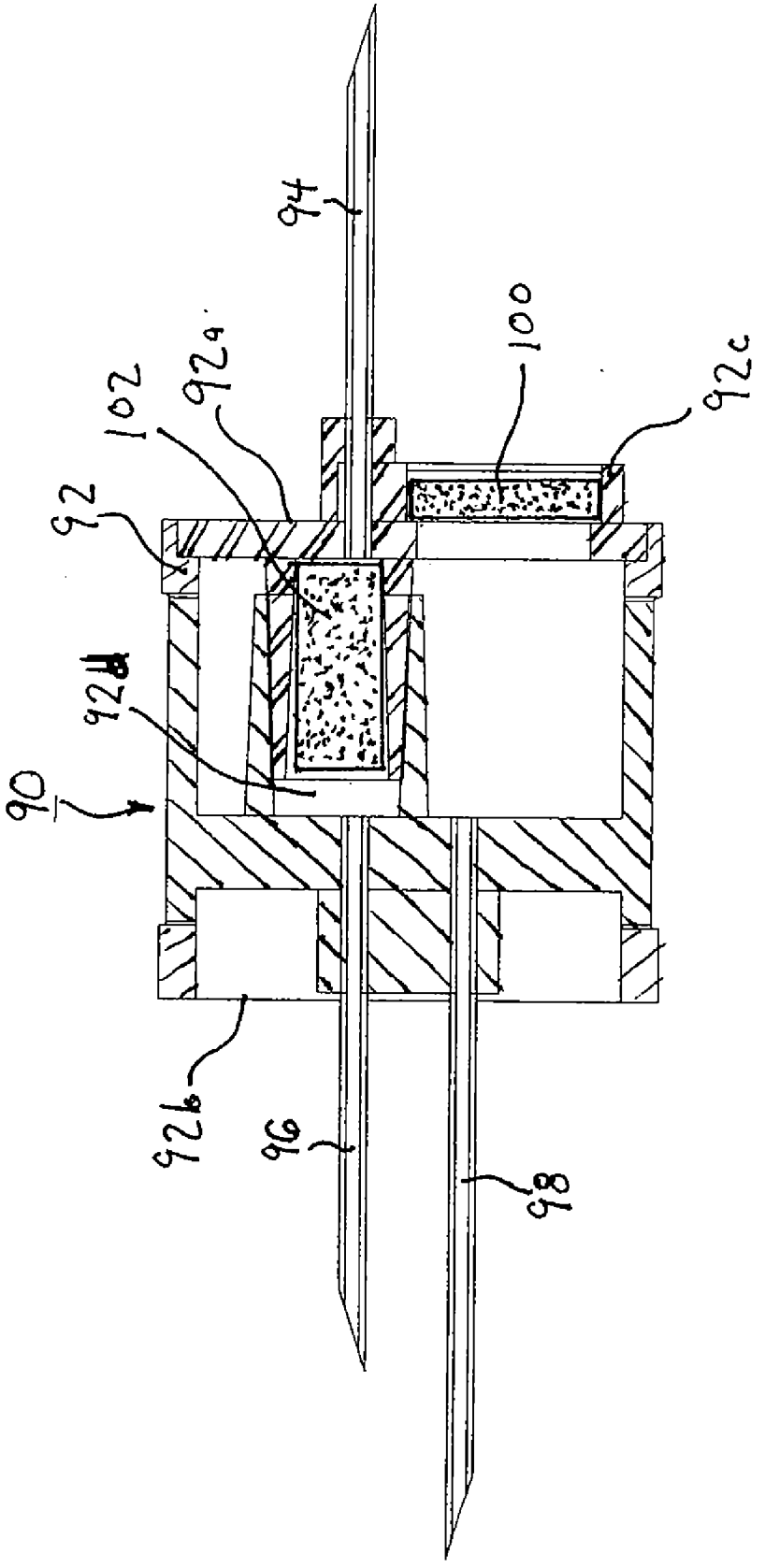

Fig. 10

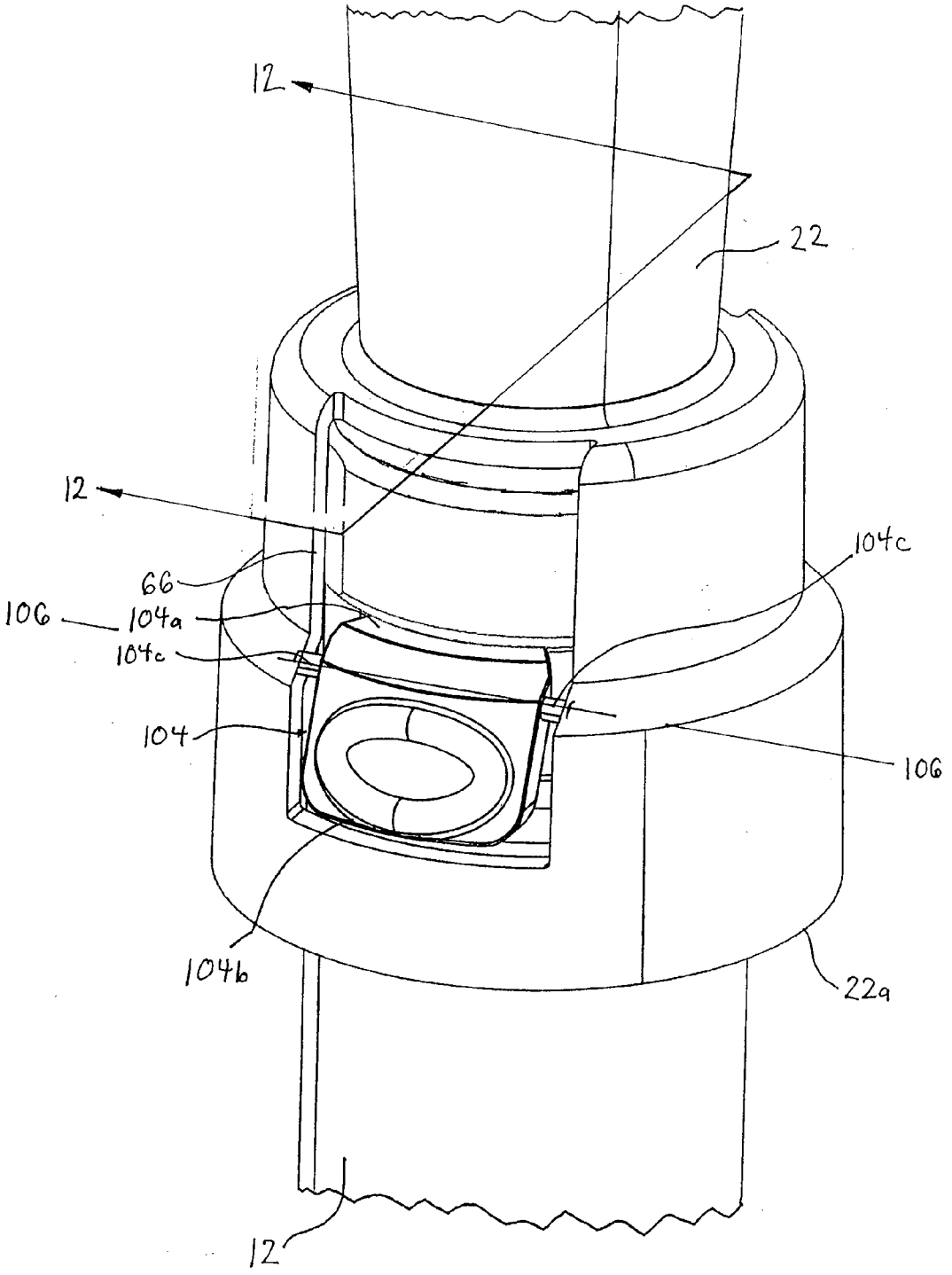

Fig. 11

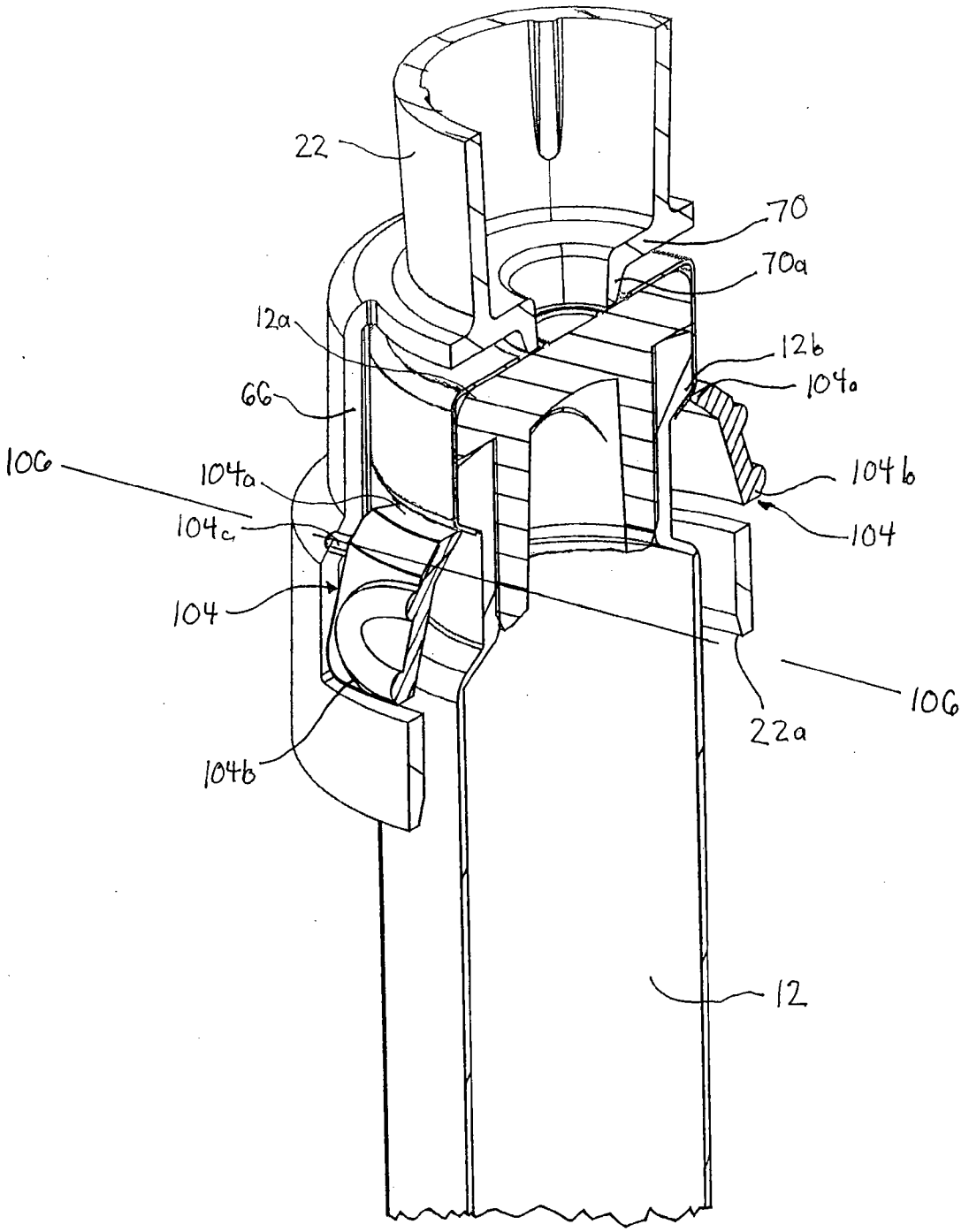
22
70
70a
12a
12b
66
104a
106
104a
104c
104b
104
104
106
22a
104b
12

Fig. 12

SYRINGE SAFETY DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a division of U.S. patent application Ser. No. 11/059,729, filed Feb. 17, 2005.

BACKGROUND OF THE INVENTION

[0002] The present application is directed to a syringe safety device for forming a fluid coupling between a sealed vial and a syringe. The syringe safety device preferably limits the exposure of a sharp needle to a user and, therefore, inadvertent pricks from the needle. The syringe safety device also provides a relatively simple process for mixing a diluent and a powdered medication to produce an injectable medication solution. It is often desirable to store drugs in a powdered form until immediately prior to administering the drug to a patient. Powdered medications typically have a longer shelf life than medications provided in a mixed or liquid solution form. Accordingly, powdered medications may be stored for a longer period of time and mixed with the diluent prior to use such that the shelf life of the medication is prolonged.

[0003] Several apparatus for transferring fluids between a vial and a syringe that generally protect a user from needle pricks have been developed. U.S. Pat. No. 6,729,370 ('370 patent) discloses a syringe safety device of this type and is incorporated herein by reference in its entirety. The syringe safety device of the '370 patent includes a connector **18** that is mountable to a vial **12** and a syringe **24** at opposing ends. A sliding joint **22** is slidably mounted in the connector **22**. A needle **20** is mounted to the sliding joint for controlled sliding movement along a connector axis. The needle is typically encompassed by the connector during use or transfer of fluid to and from the syringe and vial to prevent inadvertent needle pricks. In operation, the syringe is mounted to the sliding joint and the vial is mounted to an opposing end of the connector. The syringe is urged toward the vial along the connector axis such that the needle penetrates a stopper **16** on the vial and a diluent is dispensed into the vial. The diluent and a powdered medication in the vial are mixed, resulting in a medication solution that is drawn through the needle and into the syringe. The syringe is removed from the sliding joint and a syringe needle is mounted on the distal end of the syringe so that the medication solution is injectable into the patient.

[0004] In operation, when the mixed solution has been drawn into the syringe, the syringe is removed from the connector and the sliding joint prior to engagement with the syringe needle. During this transition, the medication solution is exposed to an external environment at a syringe orifice where the medication solution could be contaminated. In addition, the medication may leak from the syringe orifice. Accordingly, it is desirable to cover the syringe orifice so that the medication solution is generally not exposed to an external environment through the orifice.

[0005] Further, when transferring a relatively large volume of fluid to or from the vial, a significant amount of pressure or a vacuum may be created up in the vial. Accordingly, air within the vial may push a vial stopper out of the vial and escape through the stopper or between a surface of the needle and the stopper. When the large volume of mixed medication is drawn out of the vial into the syringe, a vacuum may be created in the vial. This vacuum tends to draw atmospheric air into the vial through breaches in the stopper or at the penetration of the needle. The release and introduction of air into the vial while drawing and dispensing fluid to and from the syringe may expose the fluid to contaminants. It would be desirable for all air that enters or exits the vial to be filtered and, thereby, reduce the likelihood of contamination.

BRIEF SUMMARY OF THE INVENTION

[0006] A preferred embodiment of the present invention is directed to a syringe safety device configured to form a fluid coupling between a sealed vial and a syringe having a barrel for receiving fluid. The syringe includes a luer cone extending from the barrel for dispensing or receiving fluid. The luer cone includes a distal end with a syringe orifice. The syringe safety device also includes a connector having a vial end and a syringe end. The syringe is movably mounted to the syringe end and the vial is mountable to the vial end. A tip cap is removably mounted to the luer cone of the syringe. The tip cap and the distal end define a receiving space therebetween. A needle is removably mounted to the connector and includes a needle tip facing toward the syringe in an assembled configuration. The needle tip is positioned in the receiving space when the connector and syringe are positioned in an engaged position.

[0007] In another aspect, the present invention is directed to a tip cap for a syringe that limits contact between the syringe and a needle tip, wherein the needle tip penetrates the tip cap to one of dispense medication out of the syringe and draw medication into of the syringe. The syringe includes a luer cone extending from a barrel of the syringe. The tip cap includes a penetration wall and a generally cylindrical sleeve extending generally perpendicularly from the penetration wall adjacent a periphery of the penetration wall. The cylindrical sleeve includes a radially, inwardly extending locating shoulder on an inner surface that is positioned a predetermined distance from the penetration wall. The locating shoulder engages an end of the luer cone in an operating position. The penetration wall, cylindrical sleeve and luer cone define a receiving space within which the needle tip is positionable.

[0008] In another aspect, the present invention is directed to a syringe safety device for transferring or mixing medications between a syringe and a vial. The syringe safety device includes a connector having a vial end and a syringe end. The syringe is removably mountable to the syringe end and the vial is mountable to the vial end. A tip cap is removably mountable to a luer cone of the syringe. At least one needle penetrates the tip cap in an engaged position and forms at least a portion of a fluid passageway between the syringe and vial. The tip cap is retained on the luer cone when a fluid has been transferred through the fluid passageway and the syringe is removed from the syringe end.

[0009] In yet another aspect, the present invention is directed to a method for transferring medication between a syringe having a tip cap mounted thereon and a vial. The method includes the steps of penetrating the tip cap with a needle to create a fluid passageway between the syringe and vial, drawing a medication from the vial, through the passageway and into the syringe and removing the needle from

the tip cap. The tip cap is retained on the syringe when the needle is removed from the tip cap.

[0010] In another aspect, the present invention is directed to a method of distributing a syringe safety device having a syringe with a luer cone and a plunger, a vial and a fluid transfer assembly. The fluid transfer assembly includes a connector, a sliding piston and a sliding linkage. A needle and a spike are mounted to opposing ends of the sliding linkage. The method includes the steps of at least partially filling the syringe with a diluent, mounting a tip cap to the luer cone, shipping the syringe with the tip cap thereon to a remote location, assembling the syringe with the fluid transfer assembly and delivering the assembled syringe and fluid transfer assembly to an end user.

[0011] In another aspect, the present invention is directed to a method of mixing a diluent and a powdered medication using a fluid transfer assembly. The fluid transfer assembly includes a connector, a sliding piston and a sliding linkage with a needle and a spike. The fluid transfer assembly is assembled along a connector axis. The diluent is contained in a syringe having a tip cap mounted on a luer cone of the syringe and the powered medication is contained in a vial. The method includes the steps of mounting the syringe to a syringe end of the fluid transfer assembly such that the syringe is movable relative to the fluid transfer assembly, mounting the vial to a vial end of the fluid transfer assembly, moving the syringe a first distance along the connector axis in an engaging direction at least until the needle penetrates the tip cap and is in fluid communication with the diluent, moving the syringe a second distance along the connector axis in the engaging direction at least until the spike is in fluid communication with the vial creating a fluid passageway between the syringe and vial, dispensing the diluent into the vial through the sterile fluid passageway, mixing the diluent and powdered medication in the vial which results in a medication solution, drawing the medication solution through the sterile fluid passageway into the syringe and removing the syringe from the syringe end with the tip cap being mounted on the syringe.

[0012] In another aspect, the present invention is directed to a syringe safety device configured to form a fluid coupling between a sealed vial and a syringe. The syringe safety device includes a connector for receiving the sealed vial and syringe at opposite ends thereof. The connector defines a connector axis and a sliding linkage is movably mountable on the connector axis within the connector. A needle is mounted to a first side of the sliding linkage on the connector axis and a spike is mounted to a second side of the sliding linkage on the connector axis. The spike or the needle includes a first luer lock connector that releasably mounts to a second luer lock connector of the sliding linkage.

[0013] In another aspect, the present invention is directed to a syringe safety device configured to form a fluid coupling between a vial and a syringe. The syringe safety device includes a connector having a syringe end and a vial end. The connector defines a connector axis and the syringe is removably mountable to the syringe end. The vial is mountable to the vial end and a spike is movably mounted on the connector axis to the connector. A penetration end of the spike faces the vial end for piercing a stopper of the vial in an engaged position. The penetration end has a generally figure eight-shaped cross-sectional configuration.

[0014] In a further aspect, the present invention is directed to a syringe safety device configured to form a fluid coupling between a vial and a syringe. The vial includes a head defining a peripheral rim. The syringe safety device includes a connector having a syringe end and a vial end, wherein the connector defines a connector axis. The syringe is releasably mountable to the syringe end and the vial is mountable to the vial end. The connector has a generally cylindrical-shape and includes a lock window adjacent the vial end. A vial lock extends toward the connector axis into the lock window from a root end adjacent the vial end to a terminal end. The terminal end is in engagement with the peripheral rim when the vial is mounted to the vial end.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0015] The foregoing summary, as well as the following detailed description of the preferred embodiments of the present invention, will be better understood when read in conjunction with the appended drawings. For the purposes of illustrating the syringe safety device, there is shown in the drawings preferred embodiments of the present invention. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentalities shown. In the drawings:

[0016] FIG. **1** is a perspective view of a syringe safety device in an assembled configuration in accordance with a first preferred embodiment of the present invention;

[0017] FIG. **2** is an exploded perspective view of the syringe safety device shown in FIG. **1**;

[0018] FIG. **2**A is a cross-sectional view of a tip of a spike of the syringe safety device shown in FIG. **2**, taken along line **2**A-**2**A of FIG. **2**;

[0019] FIG. **2**B is a cross-sectional view of the spike of the syringe safety device shown in FIG. **2**, taken along line **2**B-**2**B of FIG. **2**;

[0020] FIG. **3** is a cross-sectional view of the syringe safety device shown in FIG. **1** in an initial position, taken along line X-X of FIG. **1**;

[0021] FIG. **3**A is a greatly magnified fragmentary, cross-sectional view of the syringe safety device shown in FIG. **1**, taken from within the boundary of line **3**A of FIG. **3**;

[0022] FIG. **3**B is a greatly magnified fragmentary, cross-sectional view of the syringe safety device shown in FIG. **1**, taken from within the boundary of line **3**B of FIG. **3**;

[0023] FIG. **3**C is a greatly magnified fragmentary, cross-sectional view of the syringe safety device shown in FIG. **1**, taken from within the boundary of line **3**C of FIG. **3**;

[0024] FIG. **4** is a cross-sectional view of the syringe safety device shown in FIG. **1** in an intermediate position, taken along line X-X of FIG. **1**;

[0025] FIG. **5** is a cross-sectional view of the syringe safety device shown in FIG. **1** in an engaged position, taken along line X-X of FIG. **1**;

[0026] FIG. **6** is a partially exploded view of the syringe safety device shown in FIG. **1** with a luer-type needle mounted to an end of the syringe;

[0027] FIG. **7** is a greatly magnified cross-sectional view of a tip cap and a luer cone of the syringe safety device shown in FIG. **1**;

[0028] FIG. **8** is a greatly magnified perspective view of a vial end of a connector of the syringe safety device shown in FIG. **1**;

[0029] FIG. **9** is a greatly magnified perspective view of a double needle assembly in accordance with a second preferred embodiment of the syringe safety device of the present invention;

[0030] FIG. **10** is a cross-sectional view of the spike shown in FIG. **9**, taken along line **10-10** of FIG. **9**;

[0031] FIG. **11** is a greatly magnified perspective view of a vial end of a connector of the second preferred embodiment of the syringe safety device of the present invention; and

[0032] FIG. **12** is a perspective, cross-sectional view of the vial end of the connector shown in FIG. **11**, taken along line **12-12** of FIG. **11**.

DETAILED DESCRIPTION OF THE INVENTION

[0033] Certain terminology is used in the following description for convenience only and is not limiting. The words "right", "left", "lower" and "upper" designate directions in the drawings to which reference is made. The words "inwardly" and "outwardly" refer to directions toward and away from, respectively, the geometric center of the syringe safety device and designated parts thereof. The terminology includes the above-listed words, derivatives thereof and words of similar import.

[0034] Referring to the drawings in detail, wherein like numerals indicate like elements throughout, there is shown in FIGS. **1-8** a first preferred embodiment of a syringe safety device, generally designated **10**, configured to form a fluid coupling between a sealed vial **12** and a syringe **14**. The syringe **14** includes a barrel **16** for receiving fluid and a luer cone **18** extending from the barrel **16** for dispensing or receiving fluid. The luer cone **18** has a distal end **18***a* with a syringe orifice **18***b* therethrough.

[0035] The structure, configuration and operation of the syringe **14** and vial **12** are generally well known by those having ordinary skill in the art. The syringe **14** and vial **12** are typically constructed of a glass material or a transparent or translucent, generally rigid polymeric material that is generally inert or does not react with medications, diluents or other materials that are introduced into the syringe **14** and vial **12**. The structure, configuration and operation of the syringe **14** and vial **12** are not described in detail below, as being well known to those having ordinary skill in the art.

[0036] Referring to FIGS. **1**, **2**, **3-3**B and **6**, the syringe safety device **10** includes a connector **22** having a vial end **22***a* and a syringe end **22***b*. The syringe **14** is removably mountable to the syringe end **22***b* and the vial **12** is mountable to the vial end **22***a*. The connector **22** preferably has a stepped, cylindrical shape. The vial end **22** preferably has a circular cross-sectional shape that is large enough to at least partially accept the vial **12** therein or, specifically, a peripheral rim **12***b* of the vial **12**, and the syringe end **22***b* preferably has a circular cross-sectional shape that is large enough to at least partially accept the syringe **14** therein. The connector **22** is preferably constructed of an injection molded, polymeric material and includes a pair of generally rigid grip wings **24** extending generally perpendicularly from an outer surface that are integral with the connector **22**. The connector **22** is not limited to injection molded polymeric materials or to the stepped, generally cylindrical configuration shown in the drawings. The connector **22** may have nearly any shape, be processed using nearly any method and be constructed of nearly any material that results in a connector **22** that is able to perform the typical functions of the connector **22** and withstand the normal operating conditions of the connector **22**, as is described in greater detail below. The generally stepped, cylindrical shape of the connector **22** is preferred for engagement with the typically cylindrical structures of the syringe **14** and vial **12** and to shield a user from access to sharp needle tips that are positioned in the connector **22** during use. In addition, the polymeric injection molded material is preferred for the connector **22** construction due to its ease of manufacture in producing a relatively complicated shape in an economical manner. For example, the connector **22** may be constructed of an injection molded plastic material or other like materials.

[0037] Referring to FIGS. **2**, **3**A and **7**, the syringe safety device **10** also includes a tip cap **26** that is removably mountable to the luer cone **18** of the syringe **14**. The tip cap **26** and the distal end **18***a* of the luer cone **18** define a receiving space **28** in an assembled configuration. In the preferred embodiments, the tip cap **26** is constructed of a self-healing, resilient polymeric material. The tip cap **26** is not limited to self-healing, resilient polymeric materials and may be constructed of nearly any material that is able to take on the general shape, perform the typical functions and withstand the typical operating conditions of the tip cap **26**, for example, a thermoplastic elastomer or rubber-like material.

[0038] In the preferred embodiments, the tip cap **26** includes a generally cylindrical sleeve **26***a* and a generally planar penetration wall **26***b* oriented generally perpendicularly to a connector axis **30** of the syringe safety device **10** in an assembled configuration (FIGS. **3-5** and **7**). The penetration wall **26***b* is preferably positioned at one end of the cylindrical sleeve **26***a* and a tip mouth **26***d* is preferably located on an end opposite the cylindrical sleeve **26***a*. The tip cap **26** is not limited to having a generally cylindrical configuration nor to having the penetration wall **26***b* positioned at one of its ends. For example, the tip cap **26** may have a generally square or rectangular cross-section and the penetration wall **26***b* may be positioned somewhere between the two ends of the sleeve **26***a*, depending upon the configuration of the syringe **14**, the luer cone **18** of the syringe **14** and the particular application. The tip cap **26** is generally sized and shaped for mounting to the luer cone **18**, as will be described in greater detail below.

[0039] The preferred tip cap **26** includes a locating shoulder **26***c* formed on an inner surface of the sleeve **26***a*. The luer cone **18** preferably has a generally stepped, cylindrical shape and the distal end **18***a* of the luer cone **18** contacts the locating shoulder **26***c* to position the tip cap **26** relative to the distal end **18***a* in the assembled configuration. The preferred tip cap **26** includes an engaging portion **34** between the shoulder **26***c* and the tip mouth **26***d* and a receiving portion

36 between the shoulder 26*c* and penetration wall 26*b*. The engaging portion 34 preferably has a larger inner diameter than the receiving portion 36 with the locating shoulder 26*c* transitioning between the larger diameter of the engaging portion 34 and the smaller diameter of the receiving portion 36. When the tip cap 26 is mounted to the luer cone 18, the engaging portion 34 and the shoulder 26*c* are preferably in mating contact with the luer cone 18. The resilient, flexible properties of the tip cap 26 allow the tip cap 26 to engage the luer cone 18 along the engaging portion 34 such that a generally fluid-tight seal is created between the tip cap 26 and the luer cone 18. Accordingly, fluid may be contained within the barrel 16, syringe orifice 18*b* and a receiving space 28 formed in the receiving portion 36 without leakage from the syringe 14. Specifically, the tip cap 26 is preferably force fit onto the luer cone 18 of the syringe 14 such that the receiving portion 36 and penetration wall 26*b* block fluid from flowing out of the barrel 16, syringe orifice 18*b* and receiving space 28. The tip cap 26 is not limited to inclusion of separate engaging and receiving portions 34, 36 and may include a receiving space 28 having a relatively constant diameter or a receiving portion 36 having an inner diameter that is larger than the inner diameter of the engaging portion 34.

[0040] Referring to FIGS. 3-3B and 7, a needle 32 is removably mounted to the connector 22 and includes a needle tip 32*a* facing toward the syringe 14 in the assembled configuration. The needle tip 32*a* is positioned in the receiving space 28 when the connector 22 and the syringe 14 are positioned in the engaged position (FIG. 5) or in an intermediate position (FIG. 4) relative to the connector 22. In the first preferred embodiment, the needle 32 does not come into contact with the luer cone 18 in the engaged or intermediate positions. The needle tip 32 is positioned in the receiving space 28 when in the engaged position (FIG. 5) such that the needle 32 does not contact the luer cone 18. Therefore, there is generally no opportunity for the needle tip 32 to potentially become damaged or break by impacting the generally rigid luer cone 18 or damaging the luer cone 18 during an impact. Because the tip cap 26 is generally resilient and constructed of a polymeric material, the needle tip 32*a* generally easily penetrates the material of the penetration wall 26*b* of the tip cap 26, thereby generally eliminating any contact between the needle 32 and needle tip 32*a* and any rigid structure of the syringe safety device 10. This configuration allows the needle tip 32*a* to contact the fluid in the syringe 14 and create a fluid path out of the receiving space 28, syringe orifice 18*b* and barrel 16 without ever coming into contact with the rigid luer cone 18 or being positioned in the syringe orifice 18*b*.

[0041] In the first preferred embodiment, the syringe orifice 18*b*, the receiving space 28 and the needle 32 define at least a portion of a sterile fluid passageway between the syringe 14 and the vial 12 in the engaged position (FIG. 5). Therefore, the elimination of any contact between the needle 32 and the generally rigid luer cone 18 prevents impacts between the needle 32 and luer cone 18 and potential contamination of the fluid within the syringe 14 from chunks of the needle 32 or luer cone 18 that may be dislodged during an impact. In addition, inserting the needle tip 32*a* into the receiving space 28 as opposed to directly into the syringe orifice 18*b* in the engaged position permits the use of variable sized needles without concern for matching the diameter of the needle 32 to the inner diameter of the syringe orifice 18*b* or ensuring that the needle 32 will fit into the syringe orifice 18*b* regardless of its shape, without interference.

[0042] Referring to FIGS. 2, 3, 3B, 4 and 5, in the first preferred embodiment, a sliding linkage 38 is movably mounted within the connector 22 and is movable or slidable along the connector axis 30 therein. The needle 32 is preferably mounted to the sliding linkage 38. The sliding linkage 38 preferably has a generally stepped, cylindrical configuration with a needle end 38*a* and a spike end 38*b* but is not so limited. The preferred sliding linkage 38 is constructed of an injection molded, polymeric material. A linkage orifice 76 extends through the sliding linkage 38. The needle 32 is preferably adhesively bonded to the sliding linkage 38 such that a flow path is created between the needle 32 and the linkage orifice 76. The needle 32 is not limited to being adhesively bonded to the sliding linkage 38 and may be mounted to the linkage in nearly any manner including clamping, fastening or through a luer-type lock arrangement as long as the needle 32 creates a fluid path with the linkage orifice 76. In addition, the sliding linkage 38 is not limited to injection molded polymeric constructions and may be constructed of nearly any material able to take on the general shape of the sliding linkage 38 and perform the typical functions of the sliding linkage 38, as will be described in greater detail below.

[0043] Referring to FIGS. 1, 2, 3, 3A and 6, in the preferred embodiments, a sliding piston 40 is movably or slidably mounted within the connector 22 along the connector axis 30. The sliding piston 40 has a generally stepped, cylindrical-shape with a first end 40*a* and a second end 40*b*. The sliding piston 40 engages the syringe 14 at the first end 40*a* in the assembled configuration.

[0044] The sliding piston 40 is preferably constructed of an injection molded polymeric material and is preferably removably mountable to the first end 40*a* in the assembled configuration, as will be described in greater detail below. The sliding piston 40 is not limited to stepped, cylindrical shapes or to constructions comprised of injection molded polymeric materials. The sliding piston 40 preferably has a shape that is complementary to sliding engagement with the connector 22 and for removably engaging the syringe 14. The sliding piston 40 may have nearly any shape and may be constructed of nearly any material that is able to perform the typical functions of the sliding joint 40 and withstand the normal operating conditions of the sliding joint 40.

[0045] A syringe luer lock 42 is releasably mounted to the luer cone 18 of the syringe 14 in the preferred embodiments. The syringe luer lock 42 is preferably constructed of a generally resilient, polymeric material that is injection molded to form its general shape. One having ordinary skill in the art will realize that the syringe luer lock 42 is not necessary for the operation of the syringe safety device 10 and may be eliminated without significantly impacting the operation of the syringe safety device 10. However, the syringe luer lock 42 is preferred for mounting a luer needle 44 to the luer cone 18 of the syringe 14, as will be described in greater detail below.

[0046] Referring to FIG. 7, the penetration wall 26*b*, cylindrical sleeve 26*a* and luer cone 18 define the receiving space 28 within which the needle tip 32*a* is positionable. The sliding piston 40, which is mounted to the barrel 16, may aid

in aligning the needle **32** and luer cone **18** such that the needle tip **32***a* is located in the receiving space **28** in the intermediate or engaged positions. Positioning the needle tip **32***a* in the receiving space **28** is preferred because insufficient engagement of the needle **32** with the receiving space **28** prevents the creation of a fluid path between the needle **32** and receiving space **28**. In contrast, if the needle tip **32***a* penetrates the penetration wall **26***b* and moves along or generally parallel to the connector axis **30** beyond the receiving space **28**, there is a potential that the needle tip **32***a* may come into contact with and impact the luer cone **18**.

[**0047**] In the preferred embodiments, the tip cap **26** is constructed of a self-healing, polymeric material, for example, a thermoplastic elastomer or rubber-like material. The tip cap **26** is not limited to self-healing, polymeric materials; however, the self-healing material is preferred for construction of at least the penetration wall **26***b*. The self-healing material in the penetration wall **26***b* allows the penetration wall **26***b* to seal-heal after being penetrated by the needle **32** and removing the needle **32** therefrom. Accordingly, even after the needle **32** is removed from the penetration wall **26***b*, the fluid within the receiving space **28** does not leak from a hole in the penetration wall **26***b* because the penetration wall **26***b* self-heals. Self-healing materials are generally well known to those having ordinary skill in the art.

[**0048**] Referring to FIGS. **2**, **3** and **7**, the cylindrical sleeve **26***a* includes the tip mouth **26***d*, which preferably contacts the syringe luer lock **42** in the assembled configuration. Contact between the tip mouth **26***d* and the syringe luer lock **42** further positions and aligns the tip cap **26** relative to the distal end **18***a* of the luer cone **18**. That is, in addition to locating the tip cap **26** relative to the luer cone **18** using the shoulder **26***c*, the syringe luer lock **42** contacts the tip mouth **26***d* such that the tip cap **26** is engaged with the luer cone **18** at a preferred position. The location of the tip cap **26** relative to the distal end **18***a* of the luer cone **18** aids in defining the receiving space **28** such that the needle tip **32***a* may be positioned in the receiving space **28** in the intermediate and engaged positions.

[**0049**] In the preferred embodiments, an inner diameter of the cylindrical sleeve **26***a* within the engaging portion **34** tapers away from the connector axis **30** from the shoulder **26***c* to the tip mouth **26***d*. Tapering of the inner surface of the tip cap **26** in the engaging portion **34** in this manner aids in aligning the luer cone **18** relative to the tip cap **26** and promotes the engagement of the tip cap **26** with the luer cone **18** as will be obvious to one having ordinary skill in the art. The tip cap **26** is not limited to being tapered on the inner surface of the engaging portion **34** in this manner and may have a generally constant cross-section in the engaging portion **34** or nearly any cross-section that permits the tip cap **26** to engage the luer cone **18** in a generally fluid-tight manner. The preferred configuration of the tip cap **26** in the engaging portion **34**, the configuration and location of the shoulder **26***c* and the generally resilient nature of the preferred construction of the tip cap **26** allow the tip cap **26** to be force fit onto the luer cone **18** over the engaging portion **34**.

[**0050**] Referring to FIGS. **1** and **2**, the syringe safety device **10** is utilized for transferring or mixing medications between the syringe **14** and the vial **12**. In the engaged position, the needle **32** penetrates the tip cap **26**, forming at least a portion of a fluid passageway between the syringe **14** and vial **12**. The tip cap **26** is retained on the luer cone **18** when fluid in the vial **12** has been transferred through the fluid passageway into the syringe **14** and the syringe **14** is removed from the syringe end **22***b*. Accordingly, fluid or a medication that is drawn into the barrel **16** is retained in the barrel **16** by the self-healing tip cap **26**. When the syringe **14** is removed from the syringe end **22***b*, the fluid is not only retained therein, but the tip cap **26** shields the retained fluid from potential external contamination through the exposed syringe orifice **18***b*, if the tip cap **26** were not positioned on the luer cone **18**.

[**0051**] Referring to FIGS. **2**, **3**A and **6**, in the preferred embodiments, a luer needle **44** is removably mountable to the distal end **18***a* of the syringe **14** when the tip cap **26** is removed from the distal end **18***a*. When the luer needle **44** is mounted to the luer cone **18**, the syringe **14** is prepared for injecting the retained fluid or medication in the barrel **16** into a patient through the luer needle **44**. The luer needle **44** is preferably mounted to the luer cone **18** through engagement with the syringe luer lock **42**. The syringe luer lock **42** may provide a threaded engagement for mounting to the luer needle **44** or may be shaped such that the luer needle **44** is force fit onto the luer lock **42** and luer cone **18**. One having ordinary skill in the art will realize that the luer lock **42** may provide nearly any fastening mechanism to secure the luer needle **44** to the syringe **14** such that the luer needle **44** is in fluid communication with the syringe orifice **18***b* and is retained on the luer cone **18** during normal operation of the syringe **14**. For example, the luer needle **44** may be comprised of a luer slip syringe with no luer threads or a luer lock syringe having threads.

[**0052**] Referring to FIGS. **2** and **3**A, the syringe luer lock **42** is removably mountable to the luer cone **18** and may aid in aligning the syringe orifice **18***b* relative to the sliding piston **40** and the tip cap **26** relative to the syringe orifice **18***b* in the assembled configuration. Alignment of the sliding piston **40** with the tip cap **26** and the sliding linkage **38** having the needle **32** attached thereto along the connector access **30** in the assembled configuration promotes the proper alignment of the needle **32** relative to the luer cone **18** and placement of the needle tip **32***a* in receiving space **28** in the intermediate and engaged positions.

[**0053**] Referring to FIGS. **2**, **3**-**3**B, **4** and **5**, the sliding linkage **38** is movably or slidably mounted to the connector **22** along the connector axis **30**. The sliding linkage **38** includes a shoulder **38***d* adjacent the needle end **38***a* and the connector **22** includes a first locking mechanism **46** and a second locking mechanism **48** in the preferred embodiments. The sliding piston **40** also includes a shoulder **40***c* adjacent the second end **40***b* in the preferred embodiments. The shoulders **38***d*, **40***c* of the sliding linkage **38** and sliding piston **40** are preferably integral parts of the sliding linkage **38** and sliding piston **40** formed on an outer surface thereof. The shoulders **38***d*, **40***c* are preferably constructed of rings that extend outwardly from the generally cylindrical outer surface of the sliding linkage **38** and sliding piston **40**.

[**0054**] The first and second locking mechanisms **46**, **48** preferably permit the sliding linkage **38** and sliding piston **40** to move in an engaging direction along the connector axis **22** toward the vial end **22***a* and preferably prevent the sliding

linkage **38** and sliding piston **40** from moving in a release direction opposite the engaging direction beyond a first locking position (FIG. **1**) and a second locking position (FIG. **3**) once the sliding linkage **38** and sliding piston **40** have moved in the engaging direction past the first and second locking positions, respectively. That is, the sliding linkage **38** and sliding piston **40** are able to slide in the engaging direction toward the vial end **22***a* such that the shoulders **38***d*, **40***c* move to and beyond the first and second locking mechanisms **46**, **48** and pass the first and second locking positions, but are preferably unable to travel in the disengaging direction beyond the first and second locking positions once they have traveled to and beyond the first and second locking positions. The sliding linkage **38** and sliding piston **40** are preferably configured in this manner such that they are retained in the connector **22** once they are mounted in the assembled configuration and do not fall out of the connector **22** during use. However, the sliding linkage **38** and sliding piston **40** are not so limited and may be releaseable from the connector **22** for subsequent use, as will be understood by one having ordinary skill in the art. In the preferred embodiments, an audible indication or notice sounds when the shoulders **38***d*, **40***c* slide along the connector axis **30** in the engaging direction beyond the first and second locking mechanisms **46**, **48**, as will be described in greater detail below.

[**0055**] The sliding linkage **38** and sliding piston **40** are guided in their movement along the connector axis **30** by contact between the shoulders **38***d*, **40***c* or other portions of the sliding linkage **38** and sliding piston **40** and an inner surface of the connector **22**. The generally cylindrical shape of the sliding linkage **38** and sliding piston **40** and the generally hollow, cylindrical shape of the connector **22** align the sliding linkage **38** and sliding piston **40** along the connector axis **30** and permit movement of the sliding linkage **38** and sliding piston **40** along the connector axis **30**. However, the sliding linkage **38** and sliding piston **40** are not limited to being slidably mounted to the connector **22** in the above-described manner and may, for example, mount on rails (not shown) in the connector **22** or include ball bearings (not shown) that permit slidable mounting of the sliding linkage **38** and sliding piston **40** within the connector **22**.

[**0056**] Referring to FIGS. **1**, **2**, **3**, **3**A and **4**-**6**, in the preferred embodiments, the first and second locking mechanisms **46**, **48** are comprised of a first and second pair of resilient tabs **46**, **48** that are positioned in cutouts **50** in the connector **22**. The resilient tabs **46**, **48** extend inwardly from the connector **22** toward the connector axis **30** and include grasping tips **46***a*, **48***a* that are engageable with the shoulders **38***d*, **40***c*. The tabs **46**, **48** are flexible in that the grasping tips **46***a*, **48***a* are able to flex away from or toward the connector axis **30** when a force is applied to the tips **46***a*, **48***a* generally radially away from the connection axis **36**. When the sliding linkage **38** or sliding piston **40** is urged into the connector **22** in the engaging direction, the shoulders **38***d*, **40***c* urge the tips **46***a*, **48***a* away from the connector axis **30** to allow the sliding linkage **38** or sliding piston **40** to move toward the vial end **22***a*. When the shoulders **38***d*, **40***c* move beyond the grasping tips **46***a*, **48***a* in the engaging direction, the shape of the tabs **46**, **48** and shoulders **38***d*, **40***c* generally prevents the sliding linkage **38** or sliding piston **40** from moving in the disengaging direction toward the syringe end **22***b*. In the initial position (FIG. **3**) the sliding linkage **38** is engaged with the second locking mechanism **48** at its shoulder **38***d* and the sliding piston **40** is engaged with the first locking mechanism **46** at its shoulder **40***c*. Accordingly, in the initial position, the sliding linkage **38** and sliding piston **40** are generally prevented from moving in the disengaging direction toward the syringe end **22** beyond the first locking mechanism **46** or second locking mechanism **48**, respectively. Therefore, the sliding linkage **38** and sliding piston **40** are preferably secured in the connector **22** in the initial position.

[**0057**] One having ordinary skill in the art will realize that the sliding linkage **38** and sliding piston **40** are movable in the disengaging direction beyond the first and second locking mechanisms **46**, **48** by bending the tabs **46**, **48** outwardly to allow the shoulders **38***d*, **40***c* to pass beyond the grasping tips **46***a*, **48***a*. In addition, one having ordinary skill in the art will realize that the connector **22** is not limited to the specific tabs **46**, **48** having grasping tips **46***a*, **48***a* shown in the figures and may include nearly any locking mechanism that allows movement of the sliding linkage **38** and sliding piston **40** in the engaging direction along the connector axis **30** and generally prevents movement of the sliding linkage **38** and sliding piston **40** in the disengaging direction once the sliding linkage **38** and sliding piston **40** have moved beyond the first or second locking mechanisms **46**, **48** in the engaging direction.

[**0058**] Referring to FIGS. **1**, **2** and **3**A in the preferred embodiments, the syringe **14** is releasably engageable by the sliding piston **40** adjacent the luer cone **18** in the assembled configuration. The sliding piston **40** preferably aligns the syringe **14** relative to the connector **22** along the connector axis **30**. In the assembled configuration, when the sliding piston **40**, with the syringe **14** attached thereto, slides in the engaging direction such that the shoulder **40***c* is engaged by the first locking mechanism **46**, the syringe **14** may be released from the sliding piston **40** by moving the syringe **14** in the disengaging direction. The sliding piston **40** is preferably retained in the connector **22** through engagement of the first grasping tip **46***a* with the shoulder **40***c*. Accordingly, although the sliding piston **40** is generally not removed from the connector **20** by applying a force in the disengaging direction once the shoulder **40***c* is engaged with the grasping tip **46***a*, the syringe **14** may be released from the sliding piston **40** by applying a force in the disengaging direction. The tip cap **26** is preferably retained on the luer cone **18** when the syringe **14** is removed from the connector **22** and releases from the sliding piston **40**, but is not so limited. For example, the tip cap **26** may be retained in the connector **22** upon removal of the syringe **14** from the connector **22**.

[**0059**] Referring to FIGS. **1**, **2** and **3**B, the connector **22** receives the sealed vial **12** and syringe **14** at the vial end **22***a* and syringe end **22***b*, respectively, in the assembled configuration. The vial **12**, connector **22** and syringe **14** are preferably aligned along the connector axis **30** in the assembled configuration. In addition, the sliding linkage **38** and sliding piston **40** are mounted within the connector **22** along the connector axis **30** and are slidable along the connector axis **30**, typically in the engaging direction. The needle **32** is mounted to the sliding linkage **38** adjacent the needle end **38***a* and a spike **52** is mounted to the sliding linkage **38** adjacent the spike end **38***b*. The needle **32** and spike **52** are positioned generally coaxially on the connector axis **30** in the assembled configuration, but are not so limited. For example, the needle **32** and spike **52** may be

aligned generally parallel to the connector axis **30**. In the first preferred embodiment, the spike **52** includes a first or female luer lock connector **52***a* that releasably mounts to a second or male luer lock connector **54** of the sliding linkage **38**.

[**0060**] One having ordinary skill in the art will realize that the spike **52** is not limited to being luer locked to the sliding linkage **38**. For example, the spike **52** may be adhesively bonded to the sliding linkage **38**. Luer-locking the spike **52** to the sliding linkage **38** allows the spike **52** to be removed from the sliding linkage **38**, cleaned and potentially reused in an additional operation.

[**0061**] Referring to FIGS. **3**A-**3**C and **5**, in the first preferred embodiment, the spike **52** pierces the vial stopper **12***a* and the needle **32** pierces the tip cap **26** on the distal end **18***a* of the syringe **14** in the engaged position (FIG. **5**). Accordingly, when the needle **32** pierces the tip cap **26** and the spike **52** pierces the vial stopper **12***a*, a sterile fluid passageway is created between the vial **12** and syringe **14** through the needle **32**, a fluid lumen **56** in the spike **52** and the linkage orifice **76** of the sliding linkage **38**. Fluids, solutions or gases may be passed to and between the syringe **14** and vial **12** through the sterile fluid passageway.

[**0062**] Referring to FIGS. **2**-**2**B, **3**B and **5**, in the first preferred embodiment, the spike **52** includes an air filter housing **52***b* that is preferably integrally formed with the spike **52**. In addition, the spike **52** includes the fluid lumen or first channel **56** and a second channel **58**. The first channel **56** extends from a location proximate an end of the spike **52** adjacent the female luer lock connector **52***a* to a position proximate a penetration end **52***c* of the spike **52** and the second channel **58** extends from the air filter housing **52***b* to a position proximate the penetration end **52***c*. The first and second channels **56**, **58** are separate and are both preferably exposed to an internal cavity of the vial **12** beneath the vial stopper **12***a* in the engaged position. The first channel **56** preferably forms part of the sterile fluid passageway between the syringe **14** and the vial **12** in the engaged position. The second channel **58** preferably forms a fluid passageway between the vial **12** and an external environment through the filter housing **52***b*. The first and second channels **56**, **58** preferably extend generally parallel relative to each other and are generally parallel to the connection axis **30** in the assembled configuration.

[**0063**] The spike **52** is not limited to the inclusion of the second channel **58** or to the inclusion of the air filter housing **52***b*. For example, the spike **52** may be comprised of two needles (not shown) that are mounted to the sliding linkage **38**, one that forms part of the fluid passageway between the vial **12** and the syringe **14** in the engaged position and one that provides a passageway to the external environment to relieve pressure in the vial **12** during use, as will be described in greater detail below. In addition, the spike **52** may be formed with a single passageway (not shown) that forms part of the fluid passageway. This configuration is preferably utilized with vials **12** and syringes **14** having a relatively small volume where balancing the pressure inside of the vial **12** with atmosphere is often unnecessary. One having ordinary skill in the art will realize that the spike **52** may be comprised of nearly any mechanism that provides a portion of a flow path between the vial **12** and syringe **14**, is able to penetrate the vial stopper **12***a* and slide along the connector axis **30** with the sliding linkage **38**.

[**0064**] In the first preferred embodiment, an air filter **60** is mounted within the air filter housing **52***b* of the spike **52**. The air filter **60** preferably filters air passing to and from the vial **12** from the external environment through the second channel **58**. When fluid from the syringe **14** is introduced into the vial **12** through the sterile fluid passageway, air within the vial **12** is preferably forced out of the vial **12** by the incoming fluid through the second channel **58** and through the air filter **60**. Conversely, when fluid is drawn out of the vial **12** through the sterile fluid passageway and into the syringe **14**, air is drawn into the vial **12** through the air filter **60** and the second channel **58**. Drawing fluid out of the vial **12** typically creates a vacuum that draws air through the air filter **60**, through the second channel **58** and into the vial **12**. The air filter **60** is preferably able to filter external air that may potentially include contaminants that could contaminate the fluid or medication within the syringe **14** or the vial **12**. In addition, the inclusion of the second channel **58**, which provides exposure to the external environment in the engaged position, aids in stabilizing pressure within the vial **12**, which is preferred for relatively large vials **12** or the dispensing or introduction of large amounts of fluid or medication into or out of the vial **12**. The introduction of relatively large volumes of fluids into a relatively large vial **12** often creates a high pressure in the vial **12** and may damage the vial **12** or push the vial stopper **12***a* out of the vial **12** during use, thereby potentially spilling the fluid and/or medication. One having ordinary skill in the art will realize that the syringe safety device **10** is not limited to the inclusion of the air filter **60** or air filter housing **52***b* and may relieve pressure or balance the vacuum within the vial **12** simply using the second channel **58**. In addition, one having ordinary skill in the art will realize that the inclusion of the second channel **58** is not required for the operation of the syringe safety device **10** and is provided generally for relatively large vials **12**, which may be subject to relatively large pressure or vacuum variations during use.

[**0065**] Referring to FIGS. **2**-**2**B and **3**B, the penetration end **52***c* of the spike **52** faces the vial end **22***a* in the assembled configuration for piercing the vial stopper **12***a* in the engaged position. The penetration end **52***c* has a generally figure eight-shaped cross-sectional configuration (FIG. **2**A). The spike **52** includes a first bulbous region **62** and a second bulbous region **64** adjacent the penetration end **52***c*. The first channel or fluid lumen **56** is preferably positioned in the first bulbous region **62** and the second channel or air bleed lumen **58** is preferably positioned in the second bulbous region **64**. The figure eight-shaped cross-sectional configuration of the penetration end **52***c* of the spike **52** limits the cross-sectional area of the penetration end **52***c* while accommodating both the fluid lumen **56** and the air bleed lumen **58**. Construction of the spike **52** having a conventional circular cross-section at its penetration end **52***c* results in a relatively large cross-sectional area penetrating the vial stopper **12***a*. In contrast, utilization of the figure eight-shaped cross-section results in a smaller cross-sectional area that penetrates the vial stopper **12***a*. Accordingly, a hole in the vial stopper **12***a* is comparatively smaller, the force required to penetrate the vial stopper **12***a* with the spike **52** is comparatively smaller and the resulting hole in the vial stopper **12***a* that must be self-healed by the vial stopper material is comparatively smaller. In addition, the figure eight-shaped cross-sectional configuration is able to

accommodate both the fluid and air bleed lumens **56**, **58** for introduction into the vial **12** in the engaged position.

[**0066**] One having ordinary skill in the art will realize that the figure eight-shaped, cross-sectional configuration of the penetration end **52***c* of the spike **52** is not limiting and the syringe safety device **10** may operate having a spike **52** with the fluid and air bleed lumens **56**, **58** therein and a generally circular cross-section or with a spike **52** having a completely different configuration, as was described above. However, the figure eight-shaped, cross-sectional configuration is preferred for the above-stated reasons.

[**0067**] Referring to FIGS. **1**, **2**, **3**C, **6** and **8**, the connector **22** includes a lock window **66** adjacent the vial end **22***a*. A vial lock **68** extends toward the connector axis **30** into the lock window **66** from a root end **68***a* adjacent the vial end **22***a* to a terminal end **68***b*. The terminal end **68***b* is in engagement with the peripheral rim **12***d* when the vial **12** is mounted to the vial end **22***a*. The lock window **66** is preferably a generally rectangular cutout in the connector **22** adjacent the vial end **22***a* and the vial lock **68** preferably extends from an edge of the lock window **66** adjacent the vial end **22***a* to the terminal end **68***b* toward the connector axis **30**. The vial lock **68** is preferably comprised of a pair of vial lock tabs **68** that are integrally formed with the connector **22**. The vial lock tabs **68** are preferably resilient and may flex at their terminal end **68***b* toward and away from the connector axis **30**. In addition, the lock window **66** is preferably comprised of first and second windows **68** that incorporate the vial locks **68** on opposing sides of the connector **22**.

[**0068**] In the preferred embodiments, the connector **22** includes a vial shoulder **70** that is positioned on a plane generally perpendicular relative to the connector axis **30** in the assembled configuration. The vial shoulder **70** includes a spike hole **72** therein that is generally centered about the connector axis **30**. In the engaged position, the vial stopper **12***a* is preferably in facing engagement with the vial shoulder **70**. The vial shoulder **70** aids in positioning the vial **12** relative to the connector **22** when the vial **12** is mounted thereon. One having ordinary skill in the art will realize that the connector **22** is not limited to the inclusion of the vial shoulder **70**. The vial shoulder **70** is preferably provided to aid in positioning the vial **12** relative to the connector **22** and to limit access to the penetration end **52***c* of the spike **52**. In addition, the vial shoulder **70** aids in engaging or mounting the vial **12** to the connector **22** with the vial locks **68**, as will be described in greater detail below.

[**0069**] Referring to FIG. **8**, in the preferred embodiments, the vial shoulder **70** includes a ring **70***a* that defines the spike hole **72**. The ring **70***a* is preferably in facing engagement with the vial stopper **12***a* when the vial **12** is mounted to the connector **22**. The vial ring **70***a* is preferably provided for alignment and strength purposes and is not necessarily required for the operation of the syringe safety device **10**, as will be understood by one having ordinary skill in the art.

[**0070**] Referring to FIG. **3**C, the vial lock **68** preferably extends from the root end **68***a* to the terminal end **68***b* at a lock angle Δ relative to the connector axis **30**. In the first preferred embodiment, the lock angle Δ is between thirty and fifty degrees (30°-50°). The preferred vial lock **68** is resilient to permit flexure of the vial lock **68** toward and away from the connector axis **30**. Accordingly, to mount the vial **12** to the connector **22** in the first preferred embodiment, the vial **12** is urged along the connector axis **30** in the disengaging direction toward the vial shoulder **70**. As the vial stopper **12***a* nears the vial shoulder **70**, the vial lock **68** contacts the vial stopper **12***a* on opposing sides and flexes outwardly relative to the connector axis **30**. As the vial **12** moves closer to the vial shoulder **70**, the terminal end **68***b* of the vial lock **68** clears the peripheral rim **12***b* of the vial **12** and flexes toward the connector axis **30**. In the assembled configuration, the terminal end **68***b* is in engagement with the peripheral rim **12***b*. Due to the shape and construction of the vial lock **68** and the peripheral rim **12***b*, the vial **12** resists being moved away from the vial shoulder **70** once the vial **12** is engaged by the vial lock **68**.

[**0071**] In the first preferred embodiment, when the terminal end **68***b* clears the outer diameter of the peripheral rim **12***b*, the vial lock **68** snaps inwardly and creates an audible indication or a "click". The audible indication or "click" indicates that the vial **12** is secured to the connector **22** by the vial lock **68**. One having ordinary skill in the art will realize that the audible indication is desirable for providing an indication to the user when the vial **12** is properly engaged with the connector **22**. However, the audible indication is not limiting and the syringe safety device **10** will operate without the audible indication. In addition, the specific configuration of the vial lock **68** is not limiting and the vial **12** may be mounted to the connector **22** using nearly any mounting mechanism that secures the vial **12** to the vial end **22***a*, for example, clamping, mechanical fastening, adhesive bonding or other similar mounting mechanisms. For example, the connector **22** may include a pair of spring-biased tabs (not shown) similar to the vial lock **68** that are pivotally mounted proximate the vial end **22***a*. The spring biased tabs may be manually pivotable by a user to engage and/or disengage the peripheral rim **12***b* of the vial **12**. The pivotable tabs are preferred for a connector **22** that may be reused several times, such that several different vials **12** may be engaged and disengaged by the connector **22**.

[**0072**] In the first preferred embodiment, the vial lock **68** generally prevents the vial **12** from moving in a release direction along the connector axis **30** when the vial **12** is mounted to the vial end **22***a* without a force being applied to the vial lock **68** radially outwardly relative to the connector axis **30**. Due to limited access to an inner side of the vial lock **68**, an outward force is relatively difficult to apply to the vial lock **68** and the vial **12** is generally secured to the connector **22** once the vial lock **68** engages the peripheral rim **12***b*. Securing the vial **12** to the connector **22** and preventing release of the vial **12** from the connector **22** is desirable to prevent the vial **12** from disengaging from the connector **22** during use. In addition, it is preferred that the vial **12** and connector **22** are disposed of or thrown away after a single use.

[**0073**] Referring to FIGS. **1**-**6**, in operation, medication may be transferred between the syringe **14** and the vial **12** using the syringe safety device **10**. The sliding linkage **38** and sliding piston **40** are assembled along the connector axis **30** within the connector **22** in the initial position (FIG. **3**). In this position, the shoulder **38***d* of the sliding linkage **38** is engaged by the second locking mechanism **48** and the shoulder **40***c* of the sliding piston **40** is engaged by the first locking mechanism **46**. The syringe **14** with the tip cap **26** applied to the luer cone **18** is engaged along the connector

axis **30** to the first end **40***a* of the sliding piston **40** and the vial **12** is mounted to the vial end **22***a*. A force is initially applied to the syringe **14** in the engaging direction, thereby urging the syringe **14** and sliding piston **40** along the connector axis **30** toward the vial **12**. This initial movement causes the needle **32** to penetrate the tip cap **26** and position the needle tip **32***a* in the receiving space **28** in the intermediate position (FIG. **4**). Additional force is applied to the syringe **14** in the engaging direction and the sliding piston **40** engages the sliding linkage **38** at the needle end **38***a*. Additional force is applied to the syringe **14** along the connector axis **30** toward the vial **12**, urging the sliding piston **40** and sliding linkage **38** along the connector axis **30** such that the spike **52** penetrates the vial stopper **12***a*. The sterile fluid passageway is thereby created between the syringe **14** and the vial **12** in the engaged position (FIG. **5**). Medication may be drawn from the vial **12** through the sterile fluid passageway into the barrel **16** by drawing the plunger **20** along the connector axis **30** away from the vial **12**. The syringe **14** may then be withdrawn from the sliding piston **40** and the connector **22** by applying a force to the syringe **14** away from the vial **12** or in the disengaging direction along the connector axis **30**. The sliding piston **40** is preferably retained in the connector **22** through engagement of the shoulder **40***c* with the second locking mechanism **48**. The syringe **14** is released from the connector **22** with the tip cap **26** mounted thereon to retain the medication that is within the barrel **16** and protect the medication from potential contamination. The tip cap **26** may then be removed from the luer cone **18** and the luer needle **44** may be engaged with the luer cone **18** for injecting the medication into a patient.

[**0074**] Alternatively, when the vial **12** and syringe **14** are in the engaged position, a diluent **78** from the syringe **14** may be introduced into the vial **12** through the sterile fluid passageway. The vial **12** may include powdered medication **74** therein for mixing with the diluent **78**. The diluent **78** and powdered medication **74** are preferably mixed by agitating the vial **12** while the syringe safety device **10** is in the engaged position. When the diluent **78** and powdered medication **74** are sufficiently mixed, a medication solution results. The medication solution may be drawn into the syringe **14** by drawing the plunger **20** away from the vial **12** in the disengaging direction and drawing the medication solution through the sterile fluid passageway into the barrel **16**. The syringe **14** is then removed from the sliding piston **40**, the tip cap **26** is removed from the luer cone **18** and the luer needle **44** is engaged with the luer cone **18** for injecting the medication solution into the patient. The syringe safety device **10** may also be configured such that the powdered medication **74** is enclosed in the syringe **14** such that diluent may be introduced into the syringe **14** from the vial **12** for mixing of the medication in the syringe **14**.

[**0075**] Referring to FIGS. **1**, **2** and **6**, after the medication has been transferred from the vial **12** into the syringe **14** or a medication solution has been created and drawn into the syringe **14** and the syringe **14** has been removed from the sliding piston **40** and connector **22**, the connector **22**, sliding piston **40**, sliding linkage **38** and vial **12** as well as their related components may be disposed of. The sliding linkage **38**, sliding piston **40**, connector **22** and vial **12** are preferably disposable after a single use. Cleaning and/or sterilizing of these components after a single use is not preferred but may be performed and the components may be used numerous times.

[**0076**] Referring to FIGS. **1**, **2**, **3**, **3**A and **4**, in the preferred embodiments, when the sliding piston **40** slides into the connector **22** and is mounted in the initial position, an audible indication or "click" sounds informing the user that the sliding piston **40** is engaged by the connector **22**. One having ordinary skill in the art will realize that the audible indication is not required for proper operation of the syringe safety device **10** but is preferable to provide an indication to the user that the sliding piston **40** is engaged in the initial position by the connector **22**. The audible indication is preferably provided by the first locking mechanism **46** clearing the shoulder **46***c* and flexing inwardly into contact with an outer surface of the sliding piston **40**.

[**0077**] Referring to FIGS. **1** and **3**A-**5**, in the first preferred embodiment, when the penetration end **52***c* of the spike **52** is moved from the intermediate position to the engaged position, an audible indication or "click" sounds informing the user that the spike **52** and penetration end **52***a* are positioned in the vial **12** beneath the vial stopper **12***a*. In the engaged position, a fluid passageway is preferably formed between the vial **12** and syringe **14** through the syringe safety device **10**. One having ordinary skill in the art will realize that the audible indication is not required for proper operation of the syringe safety device **10** but is preferable to provide an indication to the user that the movement of the syringe **14** toward the vial **12** and subsequent penetration of the vial stopper **12***a* by the spike **52** is progressing in a normal manner between the intermediate position and the engaged position. The audible indication is preferably provided by the second locking mechanism **48** clearing the shoulder **46***c* and flexing inwardly into contact with an outer surface of the sliding piston **40**. The sliding linkage **38** is urged from the intermediate position to the engaged position through contact with the sliding piston **40** when force is applied to the syringe **14** toward the vial **12**.

[**0078**] Referring to FIGS. **1**, **3**, **3**A, **4**, **5** and **7**, the syringe safety device **10** is preferably distributed by a manufacturer by at least partially filling the syringe **14** with a diluent **78**. The tip cap **26** is then mounted to the luer cone **18** such that the diluent **78** is retained in the barrel **16**, the syringe orifice **18***b* and the receiving space **28**. The diluent filled syringe **14** is shipped with the tip cap **26** thereon to a remote location where the filled syringe **14** is assembled with a fluid transfer assembly including the connector **22** with the sliding linkage **38** and sliding piston **40** mounted therein and their associated components. The syringe **14** assembled with the fluid transfer assembly is delivered to an end user. The end user typically mounts the vial **12** with the powdered medication **74** therein onto the vial end **22***a* of the connector **22** for introduction of the diluent **16** into the vial **12**, mixes the medication solution by mixing the diluent **78** with the powdered medication **74**, draws the medication solution into the barrel **16**, removes the syringe **14** with the tip cap **26** mounted thereon, removes the tip cap **26** from the luer cone **18**, mounts the luer needle **44** onto the luer cone **18** and injects the medication solution from the syringe **14** into the patient through the luer needle **44**.

[**0079**] The vial **12** is not limited to including the powdered medication **74** therein and the syringe **14** is not limited

to including diluent therein. For example, the vial **12** may include diluent therein and the syringe **14** may include the powdered medication **74** therein or the vial **12** may include a concentrated, liquid-form medication therein and the syringe **14** may include a diluted medication therein. The process of transferring materials to and/or from the vial **12** to the syringe **14** with the above-described medications and/or diluents in the vial **12** and syringe **14** using the syringe safety device **10** will be understood by one having ordinary skill in the art.

[**0080**] Referring to FIGS. **1** and **8**, in the first preferred embodiment, when the vial **12** is mounted to the vial end **22***a* of the connector **22**, an audible indication or "click" sounds indicating to the user that the vial **12** is locked or mounted to the connector **22**. The audible indication or click sound is preferably comprised of the pair of vial locks **68** flexing inwardly and contacting a neck of the vial **12** after the vial locks **68** have cleared the peripheral rim **12***b* of the vial **12**. One having ordinary skill in the art will realize that the audible indication notifying the user that the vial **12** is mounted to the connector **22** is not limiting. The audible indication is preferred to notify the user that the vial **12** is mounted or locked to the vial end **22***a* of the connector **22** and is prepared for operation.

[**0081**] Referring to FIGS. **1**, **3**, **4** and **5**, in the preferred embodiments, once the syringe safety device **10** is in the engaged position, the diluent **78** is dispensed through the fluid passageway into the vial **12** by depressing the plunger **20** toward the vial **12** along the connector axis **30**. Depressing the plunger **20** toward the vial **12** urges the diluent **78** in the barrel **16** through the syringe orifice **18***b*, into the receiving space **28**, through the needle **32**, through the linkage orifice **76**, through a fluid filter **80** mounted in the spike **52**, through the first channel **56** and into the vial **12**. Any pressure that may be created in the vial **12** through introduction of the diluent **78** may be relieved by releasing fluid or gases through the second channel **58**, through the air filter **60** in the spike **52** and out of the air filter housing **52***b*. When it is desirable to draw the fluid within the vial **12** back into the syringe **14**, the plunger **20** is drawn along the connector axis **30** away from the vial **12**, thereby creating a vacuum in the barrel **16** to draw the fluid in the reverse direction along the fluid passageway. Any vacuum that may be created in the vial **12** by drawing the fluid in the vial **12** back into the syringe **14** may be relieved by drawing atmospheric air through the air filter **60**, through the second channel **58** and into the vial **12**. When a sufficient amount of fluid has been drawn into the barrel **16**, the syringe **14** may be removed from the connector **22** and sliding piston **40** by applying a force to the syringe **14** along the connector axis **30** away from the vial **12** in the disengaging direction. The penetration in the tip cap **26** from the needle **32** is self-healed by the material of the tip cap **26** and the fluid is retained within the barrel **26**, syringe orifice **18***b* and receiving space **28**.

[**0082**] Referring to FIG. **2**, in the preferred embodiments, when the syringe **14** with the tip cap **26** mounted thereon is shipped to a remote location, as was described above, the syringe **14** and tip cap **26** assembly is packaged in a first sterile package **82**. Prior to assembling the syringe **14** with the tip cap **26** assembled thereto to the connector **22** and the remainder of the fluid transfer assembly, the syringe **14** and tip cap **26** assembly is removed from the first sterile package **82**. The first sterile package **82** is preferred to maintain the sterility of the syringe **14**, syringe luer lock **42** and tip cap **26** prior to use. One having ordinary skill in the art will realize that the first sterile package **82** is not required for the shipment of the syringe **14** and tip cap **26** assembly. Alternatively, a plurality of syringe **14** and tip cap **26** assemblies may be transported in a single first sterile package **82** as opposed to being individually packaged or may not be shipped in a sterile package at all. It is preferred that the syringe **14** and tip cap **26** assembly remain in their sterile state prior to use to avoid any potential contamination of the diluent **78** or any medication in the barrel **16** that may come into contact with the barrel **16** or tip cap **26** prior to use.

[**0083**] In the preferred embodiments, when the syringe **14** and tip cap **26** assembly is mounted to the fluid transfer assembly, the overall assembly is packaged in a second sterile package **84** prior to delivering the assembly to an end user. The entire assembly is preferably packaged in the second sterile package **84** to generally prevent contamination of any of the components of the assembly during shipping. The end user is then able to remove the total assembly from the second sterile package **84** prior to use. Specifically, the end user typically removes the assembly from the second sterile package **84** prior to mounting the vial **12** to the vial end **22***a* of the connector **22**. One having ordinary skill in the art will realize that the syringe **14** with the tip cap **26** mounted thereon and assembled to the connector **22** is not limited to being packaged in the second sterile package **84** before shipment to an end user.

[**0084**] The assembled syringe safety device **10** may be packaged in a third sterile package **86** for shipment directly to an end user. The syringe safety device **10** may be packaged in the third sterile package **86** in the initial position (FIG. **3**) such that the device **10** is prepared for use as soon as it is removed from the third sterile package **86**. However, the components of the syringe safety device **10** may also be individually enclosed in the third sterile package **86** for assembly by the user or shipped in alternative configurations.

[**0085**] Referring to FIGS. **9** and **10**, in a second preferred embodiment, the spike **52** and sliding linkage **38** of the first preferred embodiment may be replaced in the assembly of the syringe safety device **10** by a double needle assembly **90**. The double needle assembly **90** preferably includes a double needle housing **92**, and a syringe needle **94**, a vial needle **96** and a vent needle **98** that are each mounted to the housing **92**. The syringe, vial and vent needles **94**, **96**, **98** are preferably fixed at a blunt end to the double needle housing **92** and extend in a longitudinal direction away from the housing **92** to a generally sharp tip with the syringe needle **94** extending from a first end **92***a* of the housing **92** and the vial and vent needles **96**, **98** extending from a second, opposite end **92***b*. The housing **92** also includes an air filter housing **92***c* extending from the first end **92***a* and a fluid cavity **92***d* that the blunt ends of the syringe and vial needles **94**, **96** open into. An air filter **100** is removably mountable in the air filter housing **92***c* and a fluid filter **102** is mounted in the fluid cavity **92***d*. The air filter **100** may also be permanently attached or fixed to the air filter housing **92***c*. The housing **92** is preferably constructed of an injection molded polymeric material and the needles **94**, **96**, **98** may be integrally molded into, adhesively bonded or removably secured to the double needle housing **92**.

[0086] Referring to FIGS. **2** and **3-5**, in operation, the double needle housing **92** with the syringe, vial and vent needles **94**, **96**, **98** mounted thereto and the fluid and air filters **100**, **102** mounted therein is slidably inserted into the connector **22** such that the second end **92***b* is facing the vial end **22***a*. The external surface of the double needle housing **92** is preferably constructed to mate with the first and second locking mechanisms **46**, **48** and an inner diameter of the connector **22** to slidably secure and align the housing **92** in the connector **22** along the connector axis **30**. The sliding piston **40** and syringe **14** are inserted into the syringe end **22***b* and the vial **12** is mounted to the vial end **22***a*. The syringe **14** is urged from the initial position toward the vial end **22***a* until the syringe needle **94** pierces the tip cap **26** such that the tip of the syringe needle **94** is located in the receiving space **28** and the first end **92***a* of the housing **92** is in facing engagement with the second end **40***b* of the sliding piston **40**. The syringe **14** is urged from this intermediate position toward the vial end **22***a* until the tips of the vial and vent needles **96**, **98** penetrate the vial stopper **12***a*, creating a fluid passageway between the vial **12** and syringe **14** through the vial needle **96**, the fluid cavity **92***d* and the vial needle **96**. Fluid and/or medication may be drawn through the fluid passageway and the fluid filter **102**, which generally filters contaminants or large objects as they flow through the cavity **92***d*. In addition, as a vacuum or a high pressure is formed in the vial, air is drawn into or expelled from the vial **12** through the vent needle **98** and this air passes through the air filter **100**.

[0087] Referring to FIGS. **11** and **12**, in the second preferred embodiment the vial mounting mechanism proximate the vial end **22***a* of the connector **22** includes a pair of spring feet **104** mounted in the lock windows **66**. The spring feet **104** are preferably constructed of the same polymeric material as the connector **22** and are preferably pivotally mounted to the connector **22** on a pivot axis **106**. Each of the spring feet **104** includes a grasping end **104***a*, a manipulating end **104***b* and a pair of pivot nubs **104***c* extending from sides of the feet **104** between the grasping and manipulating ends **104***a*, **104***b*. The spring feet **104** are biased toward a grasping position (FIGS. **11** and **12**) where the grasping end **104***a* is proximate the connector axis **30** and may be pivoted to an extended position, where the grasping end **104***a* is radially spaced from the connector axis **30** such that the vial stopper **12***a* may be inserted into or removed from the vial end **22***a*. The spring feet **104** are not limited to the inclusion of the pivot nubs **104***c* and may be pivotally mounted to the connector **22** by a pivot shaft or a living hinge, as would be obvious to one having ordinary skill in the art. The pivot feet **104** of the second preferred embodiment is not limited to the above-described structure and may be comprised of nearly any structure that is able to releasably mount the vial **12** to the vial end **22***a*.

[0088] In operation, a user squeezes the manipulating ends **104***b* toward the connector axis **30** such that the spring feet **104** pivot about the pivot axis **106** and the vial **12** is inserted into the vial end **22***a* until the vial stopper **12***a* is in facing engagement with the vial ring **70***a* of the vial shoulder **70**. The manipulating ends **104***b* are released and the bias force urges the spring feet **104** to pivot on the pivot axis **106**. The spring feet **104** pivot until the grasping ends **104***a* engage the vial **12** beneath the peripheral rim **12***b* to secure the vial **12** to the connector **22** and align the vial **12** along the connector axis **30**. The operation of the syringe safety device **10** then proceeds as was described above to mix and draw medication into the syringe **14**. When the contents of the vial **12** are drawn into the syringe **14**, the user again squeezes the manipulating ends **104***b* to release the vial **12** from the connector **22**. Another vial **12** may then be inserted into and secured to the vial end **22***a* of the connector **22** for additional mixing and/or transferring of medication to and from the second vial **12** and the syringe **14**. The spring feet **104** are particularly useful when a drug dose or mixture is contained in more than one vial **12** and both doses need to be injected into the patient through a single syringe **14**.

[0089] It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

We claim:

1. A tip cap for a syringe that limits contact between the syringe and a needle tip wherein the needle tip penetrates the tip cap to one of dispense medication our of the syringe and draw medication into the syringe, the syringe including a luer cone extending from a barrel, the tip cap comprising:

a penetration wall; and

a generally cylindrical sleeve extending generally perpendicularly from the penetration wall adjacent a periphery of the penetration wall, the cylindrical sleeve including a radially inwardly extending locating shoulder on an inner surface located a predetermined distance from the penetration wall, the locating shoulder engaging an end of the luer cone in an operating position, the penetration wall, cylindrical sleeve and luer cone defining a receiving space within which the needle tip is positionable.

2. The tip cap of claim 1 wherein the tip cap is constructed of a self-healing, polymeric material.

3. The tip cap of claim 1 wherein the cylindrical sleeve includes a tip mouth, the tip mouth contacting a syringe luer lock which is mounted to the luer cone in the operating position, the contact between the tip mouth and the luer lock further positioning the tip cap relative to the end of the luer cone.

4. The tip cap of claim 1 wherein an inner surface of the cylindrical sleeve on an engaging portion of the sleeve tapers away from a connector axis.

5. The tip cap of claim 1 wherein the engaging portion is force fit onto the luer cone.

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